



Mitchell E. Daniels, Jr.
Governor

Thomas W. Easterly
Commissioner

100 North Senate Avenue
Indianapolis, Indiana 46204
(317) 232-8603
(800) 451-6027
www.IN.gov/idem

TO: Interested Parties / Applicant

DATE: August 30, 2005

RE: Schwarz Pharma Manufacturing, Inc. / 071-18639-00023

FROM: Paul Dubenetzky
Chief, Permits Branch
Office of Air Quality

Notice of Decision: Approval – Effective Immediately

Please be advised that on behalf of the Commissioner of the Department of Environmental Management, I have issued a decision regarding the enclosed matter. Pursuant to IC 13-17-3-4 and 326 IAC 2, this permit modification is effective immediately, unless a petition for stay of effectiveness is filed and granted, and may be revoked or modified in accordance with the provisions of IC 13-15-7-1.

If you wish to challenge this decision, IC 4-21.5-3-7 and IC 13-15-7-3 require that you file a petition for administrative review. This petition may include a request for stay of effectiveness and must be submitted to the Office Environmental Adjudication, 100 North Senate Avenue, Government Center North, Room 1049, Indianapolis, IN 46204, **within eighteen (18) days of the mailing of this notice**. The filing of a petition for administrative review is complete on the earliest of the following dates that apply to the filing:

- (1) the date the document is delivered to the Office of Environmental Adjudication (OEA);
- (2) the date of the postmark on the envelope containing the document, if the document is mailed to OEA by U.S. mail; or
- (3) The date on which the document is deposited with a private carrier, as shown by receipt issued by the carrier, if the document is sent to the OEA by private carrier.

The petition must include facts demonstrating that you are either the applicant, a person aggrieved or adversely affected by the decision or otherwise entitled to review by law. Please identify the permit, decision, or other order for which you seek review by permit number, name of the applicant, location, date of this notice and all of the following:

- (1) the name and address of the person making the request;
- (2) the interest of the person making the request;
- (3) identification of any persons represented by the person making the request;
- (4) the reasons, with particularity, for the request;
- (5) the issues, with particularity, proposed for considerations at any hearing; and
- (6) identification of the terms and conditions which, in the judgment of the person making the request, would be appropriate in the case in question to satisfy the requirements of the law governing documents of the type issued by the Commissioner.

Pursuant to 326 IAC 2-7-18(d), any person may petition the U.S. EPA to object to the issuance of a Title V operating permit or modification within sixty (60) days of the end of the forty-five (45) day EPA review period. Such an objection must be based only on issues that were raised with reasonable specificity during the public comment period, unless the petitioner demonstrates that it was impracticable to raise such issues, or if the grounds for such objection arose after the comment period.

To petition the U.S. EPA to object to the issuance of a Title V operating permit, contact:

U.S. Environmental Protection Agency
401 M Street
Washington, D.C. 20406

If you have technical questions regarding the enclosed documents, please contact the Office of Air Quality, Permits Branch at (317) 233-0178. Callers from within Indiana may call toll-free at 1-800-451-6027, ext. 3-0178.



INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT

We make Indiana a cleaner, healthier place to live.

Mitchell E. Daniels,
Jr.
Governor

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Commissioner

100 North Senate Avenue
(800) 451-6027
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August 30, 2005

Mr. Dwight Howard
Schwarz Pharma Manufacturing, Inc.
1101 C Avenue West
Seymour, Indiana 47274

Re: 071-18639-00023
First Significant Permit Modification to
Part 70 Permit No.: T071-7162-00023

Dear Mr. Howard:

Schwarz Pharma Manufacturing, Inc. was issued a Part 70 Operating Permit T071-7162-00023 on March 25, 2002 for a batch pharmaceutical plant. A letter requesting changes to this permit was received on December 12, 2003. Pursuant to the provisions of 326 IAC 2-7-12, a significant permit modification to this permit is hereby approved as described in the attached Technical Support Document.

The modification consists of an additional Bupropion tablet production line with a thermal oxidizer and revisions to the compliance monitoring conditions of the existing baghouses.

All other conditions of the permit shall remain unchanged and in effect. Please find attached a copy of the revised permit.

Pursuant to Contract No. A305-5-65, IDEM, OAQ has assigned the processing of this application to Eastern Research Group, Inc., (ERG). Therefore, questions should be directed to Yu-Lien Chu, ERG, Morrisville, North Carolina 27560, or call (919) 468-7871 to speak directly to Ms. Chu. Questions may also be directed to Duane Van Laningham at IDEM, OAQ, 100 North Senate Avenue, Indianapolis, Indiana, 46204, or call (800) 451-6027, and ask for Duane Van Laningham, or extension 3-6878, or dial (317) 233-6878.

Sincerely,
Original signed by
Paul Dubenetzky, Chief
Permits Branch
Office of Air Quality

Attachments
ERG/YC

cc: File - Jackson County
Jackson County Health Department
Air Compliance Section Inspector - Vaughn Ison
Compliance Data Section
Administrative and Development
Technical Support and Modeling - Michele Boner





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Indianapolis, Indiana 46204
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PART 70 OPERATING PERMIT OFFICE OF AIR QUALITY

**Schwarz Pharma Manufacturing, Inc.
1101 C Avenue West
Seymour, Indiana 47274**

(herein known as the Permittee) is hereby authorized to operate subject to the conditions contained herein, the source described in Section A (Source Summary) of this permit.

This permit is issued in accordance with 326 IAC 2 and 40 CFR Part 70 Appendix A and contains the conditions and provisions specified in 326 IAC 2-7 as required by 42 U.S.C. 7401, et. seq. (Clean Air Act as amended by the 1990 Clean Air Act Amendments), 40 CFR Part 70.6, IC 13-15 and IC 13-17.

Operation Permit No.: T071-7162-00023	
Original Signed by: Janet G. McCabe, Assistant Commissioner Office of Air Quality	Issuance Date: March 25, 2002 Expiration Date: March 25, 2007

First Administrative Amendment No.: 071-17784-00023, issued February 16, 2004

First Significant Permit Modification No.: 071-18639-00023	Pages Affected: 7, 19, 33, 40, 43-44, 46
Original signed by: Paul Dubenetzky, Chief Permits Branch Office of Air Quality	Issuance Date: August 30, 2005



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SECTION A SOURCE SUMMARY

This permit is based on information requested by the Indiana Department of Environmental Management (IDEM), Office of Air Quality (OAQ). The information describing the source contained in conditions A.1 through A.3 is descriptive information and does not constitute enforceable conditions. However, the Permittee should be aware that a physical change or a change in the method of operation that may render this descriptive information obsolete or inaccurate may trigger requirements for the Permittee to obtain additional permits or seek modification of this permit pursuant to 326 IAC 2, or change other applicable requirements presented in the permit application.

A.1 General Information [326 IAC 2-7-4(c)] [326 IAC 2-7-5(15)]

The Permittee owns and operates batch pharmaceutical manufacturing facility producing liquid, capsule, and tablet pharmaceuticals.

Responsible Official:	V.P. - Manufacturing
Source Address:	1101 C Avenue West, Seymour, Indiana 47274
Mailing Address:	1101 C Avenue West, Seymour, Indiana 47274
SIC Code:	2834
County Location:	Jackson
Source Location Status:	Nonattainment for 8-hour Ozone Standard Attainment for all other criteria pollutants
Source Status:	Part 70 Permit Program Minor Source, under PSD; Major Source under Emission Offset; Major Source, Section 112 of the Clean Air Act Not 1 of 28 Source Categories

A.2 Emission Units and Pollution Control Equipment Summary [326 IAC 2-7-4(c)(3)] [326 IAC 2-7-5(15)]

This stationary source consists of the following emission units and pollution control devices:

- (a) Two (2) 20.9 MMBtu per hour natural gas-fired boilers equipped with low-NOx burners. These units were constructed in 2000.
- (b) One (1) tablet manufacturing department, constructed in 1993, consisting of
 - (1) One (1) granulation department consisting of four (4) mixers, six (6) comminuting mills and four (4) steam-heated production ovens, equipped with a baghouse for particulate matter control, identified as EFDC1.
 - (2) One (1) tablet compression department consisting of one (1) granulator, and eleven (11) tablet presses, equipped with two (2) baghouses for particulate matter control, identified as V3 and V4.
 - (3) One (1) tablet coating department consisting of two (2) hi-coaters, equipped with two (2) baghouses for particulate matter control, identified as DC04 and DC05.
- (c) One (1) capsule manufacturing department, constructed in 1993, consisting of coating pans, auger feeders and several kettles, equipped with a baghouse for particulate matter control, identified as V5.
- (d) One (1) Phase IIIA production area, identified as emission unit EFDC2. This area manufactures several products, which involve tablet formulation, compression and filling of tablets, capsules and aqueous coating of tablets. This production area is rated at 1,960.3 pounds per batch (lbs/batch) of raw material and the PM emissions are controlled by baghouse EFDC2. The Phase IIIA production area uses 660 pounds per batch

(lbs/batch) of ethanol in the coating process. The production area includes one (1) flo-coater for the application of sustained release coating, equipped with one (1) baghouses, identified as V7. These units were constructed in 2000.

- (e) Cleaning and sanitizing operations using isopropanol, bleaches, and non-solvent based sanitizing agents.
- (f) One (1) Colyte production area (identified as emission unit DC16-1), used to manufacture different types of Colyte, involving a dry mix blending operation, product container filling and labeling. This production area was constructed in 2000 and is rated at 3,956 pounds of raw material per batch (lbs/batch) and the PM emissions are controlled by baghouse DC16-1.
- (g) One (1) Bupropion production line, to be constructed in 2005, with a maximum throughput rate of 270 batches per year and 2,400 pounds of dry solids per batch, consisting of the following:
 - (1) One (1) granulation solution preparation process, consisting of the following:
 - (A) Two (2) mixers, each with a maximum capacity of 40 gallons.
 - (B) Two (2) mixers, each with a maximum capacity of 122 gallons.
 - (C) Alcohol storage drums.
 - (2) One (1) granulation and drying, screening, and blending process, using the existing baghouses V4 and V5 for particulate matter control, and exhausting to stacks EF -04 and EF-05. This process is consisted of the following:
 - (A) One (1) fluid bed dryer.
 - (B) One (1) Bohle bin, with a maximum capacity of 37 gallons.
 - (C) One (1) Bohle blender.
 - (3) One (1) tablet compression process.
 - (4) One (1) table coating preparation process.
 - (5) One (1) tablet coating process, consisted of three (3) spray guns, with a maximum throughput rate of 98,947 tablets per hour, controlled by one (1) regenerative thermal oxidizer, and exhausting to stack EF 11-2.
 - (6) One (1) tablet printing process.
 - (7) One (1) packaging process

A.3 Specifically Regulated Insignificant Activities [326 IAC 2-7-1(21)] [326 IAC 2-7-4(c)]
[326 IAC 2-7-5(15)]

This stationary source also includes the following insignificant activities which are specifically regulated, as defined in 326 IAC 2-7-1(21):

- (a) Natural gas-fired combustion sources with heat input equal to or less than ten million (10,000,000) Btu per hour, constructed between 1985 and 2000, including:

- (1) One (1) natural gas-fired boiler with maximum capacity of 4.8 MMBtu per hour [326 IAC 6-2-4];
 - (2) One (1) natural gas-fired boiler with maximum capacity of 3.6 MMBtu per hour [326 IAC 6-2-4]; and
- (b) The following equipment related to manufacturing activities not resulting in the emission of HAPs: brazing equipment, cutting torches, soldering equipment, welding equipment [326 IAC 6-3].
- (c) Paved and unpaved roads and parking lots with public access [326 IAC 6-4].
- (d) Other categories with emissions below insignificant thresholds:
- (1) A liquid pharmaceutical manufacturing facility, consisting of liquid blending, filtration, and packaging, emitting less than three (3) pounds per hour of VOC.
 - (2) One (1) product weigh-up department for weighing the tablet, capsule, and liquid departments, consisting of six (6) weigh-up rooms with drums, scoops and scales, with emissions exhausted through one (1) baghouse for particulate matter control, identified as EFDC2. Particulate matter emissions before the baghouse are less than five (5) pounds per hour [326 IAC 6-3].

A.4 Part 70 Permit Applicability [326 IAC 2-7-2]

This stationary source is required to have a Part 70 permit by 326 IAC 2-7-2 (Applicability) because it is a major source, as defined in 326 IAC 2-7-1(22).

SECTION B GENERAL CONDITIONS

B.1 Definitions [326 IAC 2-7-1]

Terms in this permit shall have the definition assigned to such terms in the referenced regulation. In the absence of definitions in the referenced regulation, the applicable definitions found in the statutes or regulations (IC 13-11, 326 IAC 1-2 and 326 IAC 2-7) shall prevail.

B.2 Permit Term [326 IAC 2-7-5(2)][326 IAC 2-1.1-9.5]

This permit is issued for a fixed term of five (5) years from the original date, as determined in accordance with IC 4-21.5-3-5(f) and IC 13-15-5-3. Subsequent revisions, modifications, or amendments of this permit do not affect the expiration date.

B.3 Enforceability [326 IAC 2-7-7]

Unless otherwise stated, all terms and conditions in this permit, including any provisions designed to limit the source's potential to emit, are enforceable by IDEM, the United States Environmental Protection Agency (U.S. EPA) and by citizens in accordance with the Clean Air Act.

B.4 Termination of Right to Operate [326 IAC 2-7-10] [326 IAC 2-7-4(a)]

The Permittee's right to operate this source terminates with the expiration of this permit unless a timely and complete renewal application is submitted at least nine (9) months prior to the date of expiration of the source's existing permit, consistent with 326 IAC 2-7-3 and 326 IAC 2-7-4(a).

B.5 Severability [326 IAC 2-7-5(5)]

The provisions of this permit are severable; a determination that any portion of this permit is invalid shall not affect the validity of the remainder of the permit.

B.6 Property Rights or Exclusive Privilege [326 IAC 2-7-5(6)(D)]

This permit does not convey any property rights of any sort or any exclusive privilege.

B.7 Duty to Supplement and Provide Information [326 IAC 2-7-4(b)] [326 IAC 2-7-5(6)(E)] [326 IAC 2-7-6(6)]

(a) The Permittee, upon becoming aware that any relevant facts were omitted or incorrect information was submitted in the permit application, shall promptly submit such supplementary facts or corrected information to:

Indiana Department of Environmental Management
Permits Branch, Office of Air Quality
100 North Senate Avenue
Indianapolis, Indiana 46204

The submittal by the Permittee does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

- (b) The Permittee shall furnish to IDEM, OAQ, within a reasonable time, any information that IDEM, OAQ, may request in writing to determine whether cause exists for modifying, revoking and reissuing, or terminating this permit, or to determine compliance with this permit. The submittal by the Permittee does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34). Upon request, the Permittee shall also furnish to IDEM, OAQ, copies of records required to be kept by this permit or, for information claimed to be confidential, the Permittee may furnish such records directly to the U. S. EPA along with a claim of confidentiality. [326 IAC 2-7-5(6)(E)]
- (c) The Permittee may include a claim of confidentiality in accordance with 326 IAC 17.1. When furnishing copies of requested records directly to U. S. EPA, the Permittee may assert a claim of confidentiality in accordance with 40 CFR 2, Subpart B.

B.8 Compliance with Permit Conditions [326 IAC 2-7-5(6)(A)] [326 IAC 2-7-5(6)(B)]

- (a) The Permittee must comply with all conditions of this permit. Noncompliance with any provisions of this permit is grounds for:
 - (1) Enforcement action;
 - (2) Permit termination, revocation and reissuance, or modification; or
 - (3) Denial of a permit renewal application.
- (b) Noncompliance with any provisions of this permit, except any provision specifically designated as not federally enforceable, constitutes a violation of the Clean Air Act.
- (c) It shall not be a defense for the Permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of this permit.
- (d) An emergency does constitute an affirmative defense in an enforcement action provided the Permittee complies with the applicable requirements set forth in Section B, Emergency Provisions.

B.9 Certification [326 IAC 2-7-4(f)] [326 IAC 2-7-6(1)] [326 IAC 2-7-5(3)(C)]

- (a) Where specifically designated by this permit or required by an applicable requirement, any application form, report, or compliance certification submitted shall contain certification by a responsible official of truth, accuracy, and completeness. This certification shall state that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.
- (b) One (1) certification shall be included, using the attached Certification Form, with each submittal requiring certification.
- (c) A responsible official is defined at 326 IAC 2-7-1(34).

B.10 Annual Compliance Certification [326 IAC 2-7-6(5)]

- (a) The Permittee shall annually submit a compliance certification report which addresses the status of the source's compliance with the terms and conditions contained in this permit, including emission limitations, standards, or work practices. The initial certification shall cover the time period from the date of final permit issuance through December 31 of the same year. All subsequent certifications shall cover the time period from January 1 to December 31 of the previous year, and shall be submitted in letter form no later than July 1 of each year to:

Indiana Department of Environmental Management
Compliance Branch, Office of Air Quality
100 North Senate Avenue
Indianapolis, Indiana 46204

and

United States Environmental Protection Agency, Region V
Air and Radiation Division, Air Enforcement Branch - Indiana (AE-17J)
77 West Jackson Boulevard
Chicago, Illinois 60604-3590

- (b) The annual compliance certification report required by this permit shall be considered timely if the date postmarked on the envelope or certified mail receipt, or affixed by the

shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAQ, on or before the date it is due.

- (c) The annual compliance certification report shall include the following:
- (1) The appropriate identification of each term or condition of this permit that is the basis of the certification;
 - (2) The compliance status;
 - (3) Whether compliance was continuous or intermittent;
 - (4) The methods used for determining the compliance status of the source, currently and over the reporting period consistent with 326 IAC 2-7-5(3); and
 - (5) Such other facts, as specified in Sections D of this permit, as IDEM, OAQ, may require to determine the compliance status of the source.

The submittal by the Permittee does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

B.11 Preventive Maintenance Plan [326 IAC 2-7-5(1),(3) and (13)] [326 IAC 2-7-6(1) and (6)]
[326 IAC 1-6-3]

- (a) If required by specific condition(s) in Section D of this permit, the Permittee shall prepare and maintain Preventive Maintenance Plans (PMPs) within ninety (90) days after issuance of this permit, including the following information on each facility:
- (1) Identification of the individual(s) responsible for inspecting, maintaining, and repairing emission control devices;
 - (2) A description of the items or conditions that will be inspected and the inspection schedule for said items or conditions; and
 - (3) Identification and quantification of the replacement parts that will be maintained in inventory for quick replacement.

If, due to circumstances beyond the Permittee's control, the PMPs cannot be prepared and maintained within the above time frame, the Permittee may extend the date an additional ninety (90) days provided the Permittee notifies:

Indiana Department of Environmental Management
Compliance Branch, Office of Air Quality
100 North Senate Avenue
Indianapolis, Indiana 46204

The PMP and the PMP extension notification do not require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

- (b) The Permittee shall implement the PMPs as necessary to ensure that failure to implement a PMP does not cause or contribute to a violation of any limitation on emissions or potential to emit.
- (c) A copy of the PMPs shall be submitted to IDEM, OAQ, upon request and within a reasonable time, and shall be subject to review and approval by IDEM, OAQ. IDEM, OAQ, may require the Permittee to revise its PMPs whenever lack of proper maintenance

- causes or contributes to any violation. The PMP does not require the certification by the “responsible official” as defined by 326 IAC 2-7-1(34).
- (d) Records of preventive maintenance shall be retained for a period of at least five (5) years. These records shall be kept at the source location for a minimum of three (3) years. The records may be stored elsewhere for the remaining two (2) years as long as they are available upon request. If the Commissioner makes a request for records to the Permittee, the Permittee shall furnish the records to the Commissioner within a reasonable time.

B.12 Emergency Provisions [326 IAC 2-7-16]

- (a) An emergency, as defined in 326 IAC 2-7-1(12), is not an affirmative defense for an action brought for noncompliance with a federal or state health-based emission limitation.
- (b) An emergency, as defined in 326 IAC 2-7-1(12), constitutes an affirmative defense to an action brought for noncompliance with a technology-based emission limitation if the affirmative defense of an emergency is demonstrated through properly signed, contemporaneous operating logs or other relevant evidence that describe the following:
- (1) An emergency occurred and the Permittee can, to the extent possible, identify the causes of the emergency;
- (2) The permitted facility was at the time being properly operated;
- (3) During the period of an emergency, the Permittee took all reasonable steps to minimize levels of emissions that exceeded the emission standards or other requirements in this permit;
- (4) For each emergency lasting one (1) hour or more, the Permittee notified IDEM, OAQ, within four (4) daytime business hours after the beginning of the emergency, or after the emergency was discovered or reasonably should have been discovered;

Telephone Number: 1-800-451-6027 (ask for Office of Air Quality, Compliance Section), or
Telephone Number: 317-233-5674 (ask for Compliance Section)
Facsimile Number: 317-233-5967

- (5) For each emergency lasting one (1) hour or more, the Permittee submitted the attached Emergency Occurrence Report Form or its equivalent, either by mail or facsimile to:

Indiana Department of Environmental Management
Compliance Branch, Office of Air Quality
100 North Senate Avenue
Indianapolis, Indiana 46204

within two (2) working days of the time when emission limitations were exceeded due to the emergency.

The notice fulfills the requirement of 326 IAC 2-7-5(3)(C)(ii) and must contain the following:

- (A) A description of the emergency;
- (B) Any steps taken to mitigate the emissions; and

(C) Corrective actions taken.

The notification which shall be submitted by the Permittee does not require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

- (6) The Permittee immediately took all reasonable steps to correct the emergency.
- (c) In any enforcement proceeding, the Permittee seeking to establish the occurrence of an emergency has the burden of proof.
- (d) This emergency provision supersedes 326 IAC 1-6 (Malfunctions). This permit condition is in addition to any emergency or upset provision contained in any applicable requirement.
- (e) IDEM, OAQ, may require that the Preventive Maintenance Plans required under 326 IAC 2-7-4-(c)(10) be revised in response to an emergency.
- (f) Failure to notify IDEM, OAQ, by telephone or facsimile of an emergency lasting more than one (1) hour in accordance with (b)(4) and (5) of this condition shall constitute a violation of 326 IAC 2-7 and any other applicable rules.
- (g) If the emergency situation causes a deviation from a technology-based limit, the Permittee may continue to operate the affected emitting facilities during the emergency provided the Permittee immediately takes all reasonable steps to correct the emergency and minimize emissions.

B.13 Permit Shield [326 IAC 2-7-15] [326 IAC 2-7-20] [326 IAC 2-7-12]

- (a) Pursuant to 326 IAC 2-7-15, the Permittee has been granted a permit shield. The permit shield provides that compliance with the conditions of this permit shall be deemed in compliance with any applicable requirements as of the date of permit issuance, provided that either the applicable requirements are included and specifically identified in this permit or the permit contains an explicit determination or concise summary of a determination that other specifically identified requirements are not applicable. The Indiana statutes from IC 13 and rules from 326 IAC, referenced in conditions in this permit, are those applicable at the time the permit was issued. The issuance or possession of this permit shall not alone constitute a defense against an alleged violation of any law, regulation or standard, except for the requirement to obtain a Part 70 permit under 326 IAC 2-7 or for applicable requirements for which a permit shield has been granted.
- This permit shield does not extend to applicable requirements which are promulgated after the date of issuance of this permit unless this permit has been modified to reflect such new requirements.
- (b) If, after issuance of this permit, it is determined that the permit is in nonconformance with an applicable requirement that applied to the source on the date of permit issuance, IDEM, OAQ, shall immediately take steps to reopen and revise this permit and issue a compliance order to the Permittee to ensure expeditious compliance with the applicable requirement until the permit is reissued. The permit shield shall continue in effect so long as the Permittee is in compliance with the compliance order.
- (c) No permit shield shall apply to any permit term or condition that is determined after issuance of this permit to have been based on erroneous information supplied in the permit application. Erroneous information means information that the Permittee knew to be false, or in the exercise of reasonable care should have been known to be false, at the time the information was submitted.

- (d) Nothing in 326 IAC 2-7-15 or in this permit shall alter or affect the following:
 - (1) The provisions of Section 303 of the Clean Air Act (emergency orders), including the authority of the U.S. EPA under Section 303 of the Clean Air Act;
 - (2) The liability of the Permittee for any violation of applicable requirements prior to or at the time of this permit's issuance;
 - (3) The applicable requirements of the acid rain program, consistent with Section 408(a) of the Clean Air Act; and
 - (4) The ability of U.S. EPA to obtain information from the Permittee under Section 114 of the Clean Air Act.
- (e) This permit shield is not applicable to any change made under 326 IAC 2-7-20(b)(2) (Sections 502(b)(10) of the Clean Air Act changes) and 326 IAC 2-7-20(c)(2) (trading based on State Implementation Plan (SIP) provisions).
- (f) This permit shield is not applicable to modifications eligible for group processing until after IDEM, OAQ, has issued the modifications. [326 IAC 2-7-12(c)(7)]
- (g) This permit shield is not applicable to minor Part 70 permit modifications until after IDEM, OAQ, has issued the modification. [326 IAC 2-7-12(b)(7)]

B.14 Prior Permits Superseded [326 IAC 2-1.1-9.5]

- (a) All terms and conditions of previous permits issued pursuant to permitting programs approved into the state implementation plan have been either
 - (1) incorporated as originally stated,
 - (2) revised, or
 - (3) deletedby this permit.
- (b) All previous registrations and permits are superseded by this permit.

B.15 Deviations from Permit Requirements and Conditions [326 IAC 2-7-5(3)(C)(ii)]

- (a) Deviations from any permit requirements (for emergencies see Section B - Emergency Provisions), the probable cause of such deviations, and any response steps or preventive measures taken shall be reported to:

Indiana Department of Environmental Management
Compliance Data Section, Office of Air Quality
100 North Senate Avenue
Indianapolis, Indiana 46204

using the attached Quarterly Deviation and Compliance Monitoring Report, or its equivalent. A deviation required to be reported pursuant to an applicable requirement that exists independent to this permit, shall be reported according to the schedule stated in the applicable requirement and does not need to be included in this report.

The Quarterly Deviation and Compliance Monitoring Report does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

- (b) A deviation is an exceedance of a permit limitation or a failure to comply with a requirement of the permit.
- (c) Emergencies shall be included in the Quarterly Deviation and Compliance Monitoring Report.

B.16 Permit Modification, Reopening, Revocation and Reissuance, or Termination
[326 IAC 2-7-5(6)(C)] [326 IAC 2-7-8(a)] [326 IAC 2-7-9]

- (a) This permit may be modified, reopened, revoked and reissued, or terminated for cause. The filing of a request by the Permittee for a Part 70 permit modification, revocation and reissuance, or termination, or of a notification of planned changes or anticipated noncompliance does not stay any condition of this permit. [326 IAC 2-7-5(6)(C)] The notification by the Permittee does require the certification by the “responsible official” as defined by 326 IAC 2-7-1(34).
- (b) This permit shall be reopened and revised under any of the circumstances listed in IC 13-15-7-2 or if IDEM, OAQ, determines any of the following:
 - (1) That this permit contains a material mistake.
 - (2) That inaccurate statements were made in establishing the emissions standards or other terms or conditions.
 - (3) That this permit must be revised or revoked to assure compliance with an applicable requirement. [326 IAC 2-7-9(a)(3)]
- (c) Proceedings by IDEM, OAQ, to reopen and revise this permit shall follow the same procedures as apply to initial permit issuance and shall affect only those parts of this permit for which cause to reopen exists. Such reopening and revision shall be made as expeditiously as practicable. [326 IAC 2-7-9(b)]
- (d) The reopening and revision of this permit, under 326 IAC 2-7-9(a), shall not be initiated before notice of such intent is provided to the Permittee by IDEM, OAQ, at least thirty (30) days in advance of the date this permit is to be reopened, except that IDEM, OAQ, may provide a shorter time period in the case of an emergency. [326 IAC 2-7-9(c)]

B.17 Permit Renewal [326 IAC 2-7-4]

- (a) The application for renewal shall be submitted using the application form or forms prescribed by IDEM, OAQ, and shall include the information specified in 326 IAC 2-7-4. Such information shall be included in the application for each emission unit at this source, except those emission units included on the trivial or insignificant activities list contained in 326 IAC 2-7-1(21) and 326 IAC 2-7-1(40). The renewal application does require the certification by the “responsible official” as defined by 326 IAC 2-7-1(34).

Request for renewal shall be submitted to:

Indiana Department of Environmental Management
Permits Branch, Office of Air Quality
100 North Senate Avenue
Indianapolis, Indiana 46204

- (b) Timely Submittal of Permit Renewal [326 IAC 2-7-4(a)(1)(D)]
- (1) A timely renewal application is one that is:
- (A) Submitted at least nine (9) months prior to the date of the expiration of this permit; and
- (B) If the date postmarked on the envelope or certified mail receipt, or affixed by the shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAQ, on or before the date it is due.
- (2) If IDEM, OAQ, upon receiving a timely and complete permit application, fails to issue or deny the permit renewal prior to the expiration date of this permit, this existing permit shall not expire and all terms and conditions shall continue in effect, including any permit shield provided in 326 IAC 2-7-15, until the renewal permit has been issued or denied.
- (c) Right to Operate After Application for Renewal [326 IAC 2-7-3]
If the Permittee submits a timely and complete application for renewal of this permit, the source's failure to have a permit is not a violation of 326 IAC 2-7 until IDEM, OAQ, takes final action on the renewal application, except that this protection shall cease to apply if, subsequent to the completeness determination, the Permittee fails to submit by the deadline specified in writing by IDEM, OAQ, any additional information identified as being needed to process the application.
- (d) United States Environmental Protection Agency Authority [326 IAC 2-7-8(e)]
If IDEM, OAQ, fails to act in a timely way on a Part 70 permit renewal, the U.S. EPA may invoke its authority under Section 505(e) of the Clean Air Act to terminate or revoke and reissue a Part 70 permit.

B.18 Permit Amendment or Modification [326 IAC 2-7-11] [326 IAC 2-7-12]

- (a) Permit amendments and modifications are governed by the requirements of 326 IAC 2-7-11 or 326 IAC 2-7-12 whenever the Permittee seeks to amend or modify this permit.
- (b) Any application requesting an amendment or modification of this permit shall be submitted to:
- Indiana Department of Environmental Management
Permits Branch, Office of Air Quality
100 North Senate Avenue
Indianapolis, Indiana 46204
- Any such application shall be certified by the "responsible official" as defined by 326 IAC
- (c) The Permittee may implement administrative amendment changes addressed in the request for an administrative amendment immediately upon submittal of the request. [326 IAC 2-7-11(c)(3)]

B.19 Permit Revision Under Economic Incentives and Other Programs [326 IAC 2-7-5(8)]
[326 IAC 2-7-12 (b)(2)]

- (a) No Part 70 permit revision shall be required under any approved economic incentives, marketable Part 70 permits, emissions trading, and other similar programs or processes for changes that are provided for in a Part 70 permit.
- (b) Notwithstanding 326 IAC 2-7-12(b)(1)(D)(i) and 326 IAC 2-7-12(c)(1), minor Part 70 permit modification procedures may be used for Part 70 modifications involving the use of economic incentives, marketable Part 70 permits, emissions trading, and other similar approaches to the extent that such minor Part 70 permit modification procedures are explicitly provided for in the applicable State Implementation Plan (SIP) or in applicable requirements promulgated or approved by the U.S. EPA.

B.20 Operational Flexibility [326 IAC 2-7-20] [326 IAC 2-7-10.5]

- (a) The Permittee may make any change or changes at the source that are described in 326 IAC 2-7-20(b), (c), or (e), without a prior permit revision, if each of the following conditions is met:
 - (1) The changes are not modifications under any provision of Title I of the Clean Air Act;
 - (2) Any preconstruction approval required by 326 IAC 2-7-10.5 has been obtained;
 - (3) The changes do not result in emissions which exceed the emissions allowable under this permit (whether expressed herein as a rate of emissions or in terms of total emissions);
 - (4) The Permittee notifies the:

Indiana Department of Environmental Management
Permits Branch, Office of Air Quality
100 North Senate Avenue
Indianapolis, Indiana 46204

and

United States Environmental Protection Agency, Region V
Air and Radiation Division, Regulation Development Branch - Indiana (AR-18J)
77 West Jackson Boulevard
Chicago, Illinois 60604-3590

in advance of the change by written notification at least ten (10) days in advance of the proposed change. The Permittee shall attach every such notice to the Permittee's copy of this permit; and
 - (5) The Permittee maintains records on-site which document, on a rolling five (5) year basis, all such changes and emissions trading that are subject to 326 IAC 2-7-20(b), (c), or (e) and makes such records available, upon reasonable request, for public review.

Such records shall consist of all information required to be submitted to IDEM, OAQ, in the notices specified in 326 IAC 2-7-20(b), (c)(1), and (e)(2).
- (b) The Permittee may make Section 502(b)(10) of the Clean Air Act changes (this term is defined at 326 IAC 2-7-1(36)) without a permit revision, subject to the constraint of 326

IAC 2-7-20(a). For each such Section 502(b)(10) of the Clean Air Act change, the required written notification shall include the following:

- (1) A brief description of the change within the source;
- (2) The date on which the change will occur;
- (3) Any change in emissions; and
- (4) Any permit term or condition that is no longer applicable as a result of the change.

The notification which shall be submitted is not considered an application form, report or compliance certification. Therefore, the notification by the Permittee does not require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

- (c) Emission Trades [326 IAC 2-7-20(c)]
The Permittee may trade increases and decreases in emissions in the source, where the applicable SIP provides for such emission trades without requiring a permit revision, subject to the constraints of Section (a) of this condition and those in 326 IAC 2-7-20(c).
- (d) Alternative Operating Scenarios [326 IAC 2-7-20(d)]
The Permittee may make changes at the source within the range of alternative operating scenarios that are described in the terms and conditions of this permit in accordance with 326 IAC 2-7-5(9). No prior notification of IDEM, OAQ, or U.S. EPA is required.

B.21 Source Modification Requirement [326 IAC 2-7-10.5]

A modification, construction, or reconstruction is governed by 326 IAC 2 and 326 IAC 2-7-10.5.

B.22 Inspection and Entry [326 IAC 2-7-6] [IC 13-14-2-2]

Upon presentation of proper identification cards, credentials, and other documents as may be required by law, and subject to the Permittee's right under all applicable laws and regulations to assert that the information collected by the agency is confidential and entitled to be treated as such, the Permittee shall allow IDEM, OAQ, U.S. EPA, or an authorized representative to perform the following:

- (a) Enter upon the Permittee's premises where a Part 70 source is located, or emissions related activity is conducted, or where records must be kept under the conditions of this permit;
- (b) Have access to and copy any records that must be kept under the conditions of this permit;
- (c) Inspect any facilities, equipment (including monitoring and air pollution control equipment), practices, or operations regulated or required under this permit;
- (d) Sample or monitor substances or parameters for the purpose of assuring compliance with this permit or applicable requirements; and
- (e) Utilize any photographic, recording, testing, monitoring, or other equipment for the purpose of assuring compliance with this permit or applicable requirements.

B.23 Transfer of Ownership or Operational Control [326 IAC 2-7-11]

- (a) The Permittee must comply with the requirements of 326 IAC 2-7-11 whenever the Permittee seeks to change the ownership or operational control of the source and no other change in the permit is necessary.

- (b) Any application requesting a change in the ownership or operational control of the source shall contain a written agreement containing a specific date for transfer of permit responsibility, coverage and liability between the current and new Permittee. The application shall be submitted to:

Indiana Department of Environmental Management
Permits Branch, Office of Air Quality
100 North Senate Avenue
Indianapolis, Indiana 46206-6015

The application which shall be submitted by the Permittee does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

- (c) The Permittee may implement administrative amendment changes addressed in the request for an administrative amendment immediately upon submittal of the request. [326 IAC 2-7-11(c)(3)]

B.24 Annual Fee Payment [326 IAC 2-7-19] [326 IAC 2-7-5(7)]

- (a) The Permittee shall pay annual fees to IDEM, OAQ, within thirty (30) calendar days of receipt of a billing. Pursuant to 326 IAC 2-7-19(b), if the Permittee does not receive a bill from IDEM, OAQ, the applicable fee is due April 1 of each year.
- (b) Except as provided in 326 IAC 2-7-19(e), failure to pay may result in administrative enforcement action or revocation of this permit.
- (c) The Permittee may call the following telephone numbers: 1-800-451-6027 or 317-233-0425 (ask for OAQ, Billing, Licensing, and Training Section), to determine the appropriate permit fee.

B.25 Credible Evidence [326 IAC 2-7-5(3)][326 IAC 2-7-6][62 FR 8314][326 IAC 1-1-6]

For the purpose of submitting compliance certifications or establishing whether or not the Permittee has violated or is in violation of any condition of this permit, nothing in this permit shall preclude the use, including the exclusive use, of any credible evidence or information relevant to whether the Permittee would have been in compliance with the condition of this permit if the appropriate performance or compliance test or procedure had been performed. .

SECTION C

SOURCE OPERATION CONDITIONS

Entire Source

Emission Limitations and Standards [326 IAC 2-7-5(1)]

C.1 Particulate Matter Emission Limitations For Processes with Process Weight Rates Less Than One Hundred (100) Pounds per Hour Pursuant to 326 IAC 6-3-2(c), the allowable particulate matter emissions rate from any process not already regulated by 326 IAC 6-1 or any New Source Performance Standard, and which has a maximum process weight rate less than 100 pounds per hour shall not exceed 0.551 pounds per hour.

C.2 Opacity [326 IAC 5-1]
Pursuant to 326 IAC 5-1-2 (Opacity Limitations), except as provided in 326 IAC 5-1-3 (Temporary Alternative Opacity Limitations), opacity shall meet the following, unless otherwise stated in this permit:

- (a) Opacity shall not exceed an average of forty percent (40%) in any one (1) six (6) minute averaging period as determined in 326 IAC 5-1-4.
- (b) Opacity shall not exceed sixty percent (60%) for more than a cumulative total of fifteen (15) minutes (sixty (60) readings as measured according to 40 CFR 60, Appendix A, Method 9 or fifteen (15) one (1) minute nonoverlapping integrated averages for a continuous opacity monitor) in a six (6) hour period.

C.3 Open Burning [326 IAC 4-1] [IC 13-17-9]

The Permittee shall not open burn any material except as provided in 326 IAC 4-1-3, 326 IAC 4-1-4 or 326 IAC 4-1-6. The previous sentence notwithstanding, the Permittee may open burn in accordance with an open burning approval issued by the Commissioner under 326 IAC 4-1-4.1. 326 IAC 4-1-3 (a)(2)(A) and (B) are not federally enforceable.

C.4 Incineration [326 IAC 4-2] [326 IAC 9-1-2]

The Permittee shall not operate an incinerator or incinerate any waste or refuse except as provided in 326 IAC 4-2 and 326 IAC 9-1-2. 326 IAC 9-1-2 is not federally enforceable.

C.5 Fugitive Dust Emissions [326 IAC 6-4]

The Permittee shall not allow fugitive dust to escape beyond the property line or boundaries of the property, right-of-way, or easement on which the source is located, in a manner that would violate 326 IAC 6-4 (Fugitive Dust Emissions). 326 IAC 6-4-2(4) is not federally enforceable.

C.6 Operation of Equipment [326 IAC 2-7-6(6)]

Except as otherwise provided by statute or rule, or in this permit, all air pollution control equipment listed in this permit and used to comply with an applicable requirement shall be operated at all times that the emission units vented to the control equipment are in operation.

C.7 Asbestos Abatement Projects [326 IAC 14-10] [326 IAC 18] [40 CFR 61, Subpart M]

- (a) Notification requirements apply to each owner or operator. If the combined amount of regulated asbestos containing material (RACM) to be stripped, removed or disturbed is at least 260 linear feet on pipes or 160 square feet on other facility components, or at least thirty-five (35) cubic feet on all facility components, then the notification requirements of 326 IAC 14-10-3 are mandatory. All demolition projects require notification whether or not asbestos is present.

- (b) The Permittee shall ensure that a written notification is sent on a form provided by the Commissioner at least ten (10) working days before asbestos stripping or removal work or before demolition begins, per 326 IAC 14-10-3, and shall update such notice as necessary, including, but not limited to the following:
 - (1) When the amount of affected asbestos containing material increases or decreases by at least twenty percent (20%); or
 - (2) If there is a change in the following:
 - (A) Asbestos removal or demolition start date;
 - (B) Removal or demolition contractor; or
 - (C) Waste disposal site.
- (c) The Permittee shall ensure that the notice is postmarked or delivered according to the guidelines set forth in 326 IAC 14-10-3(2).
- (d) The notice to be submitted shall include the information enumerated in 326 IAC 14-10-3(3).

All required notifications shall be submitted to:

Indiana Department of Environmental Management
Asbestos Section, Office of Air Quality
100 North Senate Avenue
Indianapolis, Indiana 46204

The notice shall include a signed certification from the owner or operator that the information provided in this notification is correct and that only Indiana Licensed workers and project supervisors will be used to implement the asbestos removal project. The notifications do not require a certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

- (e) **Procedures for Asbestos Emission Control**
The Permittee shall comply with the applicable emission control procedures in 326 IAC 14-10-4 and 40 CFR 61.145(c). Per 326 IAC 14-10-4, emission control requirements are applicable for any removal or disturbance of RACM greater than three (3) linear feet on pipes or three (3) square feet on any other facility components or a total of at least 0.75 cubic feet on all facility components.
- (f) **Indiana Accredited Asbestos Inspector**
The Permittee shall comply with 326 IAC 14-10-1(a) that requires the owner or operator, prior to a renovation/demolition, to use an Indiana Accredited Asbestos Inspector to thoroughly inspect the affected portion of the facility for the presence of asbestos. The requirement that the inspector be accredited, pursuant to the provisions of 40 CFR 61, Subpart M, is federally enforceable.

Testing Requirements [326 IAC 2-7-6(1)]

C.8 Performance Testing [326 IAC 3-6]

- (a) All testing shall be performed according to the provisions of 326 IAC 3-6 (Source Sampling Procedures), except as provided elsewhere in this permit, utilizing any applicable procedures and analysis methods specified in 40 CFR 51, 40 CFR 60, 40 CFR 61, 40 CFR 63, 40 CFR 75, or other procedures approved by IDEM, OAQ.

A test protocol, except as provided elsewhere in this permit, shall be submitted to:

Indiana Department of Environmental Management
Compliance Data Section, Office of Air Quality
100 North Senate Avenue
Indianapolis, Indiana 46204

no later than thirty-five (35) days prior to the intended test date. The protocol submitted by the Permittee does not require certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

- (b) The Permittee shall notify IDEM, OAQ of the actual test date at least fourteen (14) days prior to the actual test date. The notification submitted by the Permittee does not require certification by the "responsible official" as defined by 326 IAC 2-7-1(34).
- (c) Pursuant to 326 IAC 3-6-4(b), all test reports must be received by IDEM, OAQ not later than forty-five (45) days after the completion of the testing. An extension may be granted by IDEM, OAQ, if the source submits to IDEM, OAQ, a reasonable written explanation not later than five (5) days prior to the end of the initial forty-five (45) day period.

Compliance Requirements [326 IAC 2-1.1-11]

C.9 Compliance Requirements [326 IAC 2-1.1-11]

The commissioner may require stack testing, monitoring, or reporting at any time to assure compliance with all applicable requirements. Any monitoring or testing shall be performed in accordance with 326 IAC 3 or other methods approved by the commissioner or the U. S. EPA.

Compliance Monitoring Requirements [326 IAC 2-7-5(1)] [326 IAC 2-7-6(1)]

C.10 Compliance Monitoring [326 IAC 2-7-5(3)] [326 IAC 2-7-6(1)]

Unless otherwise specified in this permit, all monitoring and record keeping requirements not already legally required shall be implemented within ninety (90) days of permit issuance. If required by Section D, the Permittee shall be responsible for installing any necessary equipment and initiating any required monitoring related to that equipment. If due to circumstances beyond its control, that equipment cannot be installed and operated within ninety (90) days, the Permittee may extend the compliance schedule related to the equipment for an additional ninety (90) days provided the Permittee notifies:

Indiana Department of Environmental Management
Compliance Branch, Office of Air Quality
100 North Senate Avenue
Indianapolis, Indiana 46204

in writing, prior to the end of the initial ninety (90) day compliance schedule, with full justification of the reasons for the inability to meet this date.

The notification which shall be submitted by the Permittee does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

Unless otherwise specified in the approval for the new emission unit(s), compliance monitoring for new emission units or emission units added through a source modification shall be implemented when operation begins.

C.11 Maintenance of Continuous Emission Monitoring Equipment [326 IAC 2-7-5(3)(A)(iii)]

- (a) The Permittee shall install, calibrate, maintain, and operate all necessary continuous emission monitoring systems (CEMS) and related equipment.
- (b) In the event that a breakdown of a continuous emission monitoring system occurs, a record shall be made of the times and reasons of the breakdown and efforts made to correct the problem.
- (c) Nothing in this permit shall excuse the Permittee from complying with the requirements to operate a continuous emission monitoring system pursuant to 40 CFR 63, Subpart GGG.

C.12 Monitoring Methods [326 IAC 3] [40 CFR 60] [40 CFR 63]

Any monitoring or testing required by Section D of this permit shall be performed according to the provisions of 326 IAC 3, 40 CFR 60, Appendix A, 40 CFR 60 Appendix B, 40 CFR 63, or other approved methods as specified in this permit.

C.13 Pressure Gauge and Other Instrument Specifications [326 IAC 2-1.1-11] [326 IAC 2-7-5(3)] [326 IAC 2-7-6(1)]

- (a) Whenever a condition in this permit requires the measurement of pressure drop across any part of the unit or its control device, the gauge employed shall have a scale such that the expected normal reading shall be no less than twenty percent (20%) of full scale and be accurate within plus or minus two percent ($\pm 2\%$) of full scale reading.
- (b) The Permittee may request the IDEM, OAQ approve the use of a pressure gauge or other instrument that does not meet the above specifications provided the Permittee can demonstrate an alternative pressure gauge or other instrument specification will adequately ensure compliance with permit conditions requiring the measurement of pressure drop or other parameters.

Corrective Actions and Response Steps [326 IAC 2-7-5] [326 IAC 2-7-6]

C.14 Emergency Reduction Plans [326 IAC 1-5-2] [326 IAC 1-5-3]

Pursuant to 326 IAC 1-5-2 (Emergency Reduction Plans; Submission):

- (a) The Permittee shall prepare written emergency reduction plans (ERPs) consistent with safe operating procedures.
- (b) These ERPs shall be submitted for approval to:

Indiana Department of Environmental Management
Compliance Branch, Office of Air Quality
100 North Senate Avenue
Indianapolis, Indiana 46204

within ninety (90) days after the date of issuance of this permit.

The ERP does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

- (c) If the ERP is disapproved by IDEM, OAQ, the Permittee shall have an additional thirty (30) days to resolve the differences and submit an approvable ERP.
- (d) These ERPs shall state those actions that will be taken, when each episode level is declared, to reduce or eliminate emissions of the appropriate air pollutants.

- (e) Said ERPs shall also identify the sources of air pollutants, the approximate amount of reduction of the pollutants, and a brief description of the manner in which the reduction will be achieved.
- (f) Upon direct notification by IDEM, OAQ, that a specific air pollution episode level is in effect, the Permittee shall immediately put into effect the actions stipulated in the approved ERP for the appropriate episode level. [326 IAC 1-5-3]

C.15 Risk Management Plan [326 IAC 2-7-5(12)] [40 CFR 68.215]

If a regulated substance, subject to 40 CFR 68, is present at a source in more than a threshold quantity, 40 CFR 68 is an applicable requirement and the Permittee shall submit:

- (a) A compliance schedule for meeting the requirements of 40 CFR 68; or
- (b) As a part of the annual compliance certification submitted under 326 IAC 2-7-6(5), a certification statement that the source is in compliance with all the requirements of 40 CFR 68, including the registration and submission of a Risk Management Plan (RMP);

All documents submitted pursuant to this condition shall include the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

C.16 Compliance Response Plan - Preparation, Implementation, Records, and Reports [326 IAC 2-7-5] [326 IAC 2-7-6]

-
- (a) The Permittee is required to prepare a Compliance Response Plan (CRP) for each compliance monitoring condition of this permit. A CRP shall be submitted to IDEM, OAQ upon request. The CRP shall be prepared within ninety (90) days after issuance of this permit by the Permittee, supplemented from time to time by the Permittee, maintained on site, and comprised of:
 - (1) Reasonable response steps that may be implemented in the event that a response step is needed pursuant to the requirements of Section D of this permit; and an expected timeframe for taking reasonable response steps.
 - (2) If, at any time, the Permittee takes reasonable response steps that are not set forth in the Permittee's current Compliance Response Plan and the Permittee documents such response in accordance with subsection (e) below, the Permittee shall amend its Compliance Response Plan to include such response steps taken.
 - (b) For each compliance monitoring condition of this permit, reasonable response steps shall be taken when indicated by the provisions of that compliance monitoring condition as follows:
 - (1) Reasonable response steps shall be taken as set forth in the Permittee's current Compliance Response Plan; or
 - (2) If none of the reasonable response steps listed in the Compliance Response Plan is applicable or responsive to the excursion, the Permittee shall devise and implement additional response steps as expeditiously as practical. Taking such additional response steps shall not be considered a deviation from this permit so long as the Permittee documents such response steps in accordance with this condition.
 - (3) If the Permittee determines that additional response steps would necessitate that the emissions unit or control device be shut down, the IDEM, OAQ shall be promptly notified of the expected date of the shut down, the status of the

applicable compliance monitoring parameter with respect to normal, and the results of the actions taken up to the time of notification.

- (4) Failure to take reasonable response steps shall constitute a violation of the permit.
- (c) The Permittee is not required to take any further response steps for any of the following reasons:
 - (1) A false reading occurs due to the malfunction of the monitoring equipment and prompt action was taken to correct the monitoring equipment.
 - (2) The Permittee has determined that the compliance monitoring parameters established in the permit conditions are technically inappropriate, has previously submitted a request for a minor permit modification to the permit, and such request has not been denied.
 - (3) An automatic measurement was taken when the process was not operating.
 - (4) The process has already returned or is returning to operating within "normal" parameters and no response steps are required.
- (d) When implementing reasonable steps in response to a compliance monitoring condition, if the Permittee determines that an exceedance of an emission limitation has occurred, the Permittee shall report such deviations pursuant to Section B-Deviations from Permit Requirements and Conditions.
- (e) The Permittee shall record all instances when response steps are taken. In the event of an emergency, the provisions of 326 IAC 2-7-16 (Emergency Provisions) requiring prompt corrective action to mitigate emissions shall prevail.
- (f) Except as otherwise provided by a rule or provided specifically in Section D, all monitoring as required in Section D shall be performed when the emission unit is operating, except for time necessary to perform quality assurance and maintenance activities.

C.17 Actions Related to Noncompliance Demonstrated by a Stack Test [326 IAC 2-7-5]
[326 IAC 2-7-6]

- (a) When the results of a stack test performed in conformance with Section C - Performance Testing, of this permit exceed the level specified in any condition of this permit, the Permittee shall take appropriate response actions. The Permittee shall submit a description of these response actions to IDEM, OAQ, within thirty (30) days of receipt of the test results. The Permittee shall take appropriate action to minimize excess emissions from the affected facility while the response actions are being implemented.
- (b) A retest to demonstrate compliance shall be performed within one hundred twenty (120) days of receipt of the original test results. Should the Permittee demonstrate to IDEM, OAQ that retesting in one-hundred and twenty (120) days is not practicable, IDEM, OAQ may extend the retesting deadline.
- (c) IDEM, OAQ reserves the authority to take any actions allowed under law in response to noncompliant stack tests.

The documents submitted pursuant to this condition do require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

Record Keeping and Reporting Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-19]

C.18 Emission Statement [326 IAC 2-7-5(3)(C)(iii)] [326 IAC 2-7-5(7)] [326 IAC 2-7-19(c)] [326 IAC 2-6]

(a) The Permittee shall submit an annual emission statement certified pursuant to the requirements of 326 IAC 2-6, that must be received by July 1 of each year and must comply with the minimum requirements specified in 326 IAC 2-6-4. The annual emission statement shall meet the following requirements:

- (1) Indicate estimated actual emissions of criteria pollutants from the source, in compliance with 326 IAC 2-6 (Emission Reporting);
- (2) Indicate estimated actual emissions of other regulated pollutants (as defined by 326 IAC 2-7-1) from the source, for purposes of Part 70 fee assessment.

(b) The annual emission statement covers the twelve (12) consecutive month time period starting January 1 and ending December 31. The annual emission statement must be submitted to:

Indiana Department of Environmental Management
Technical Support and Modeling Section, Office of Air Quality
100 North Senate Avenue
Indianapolis, Indiana 46204

The emission statement does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

(c) The annual emission statement required by this permit shall be considered timely if the date postmarked on the envelope or certified mail receipt, or affixed by the shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAQ, on or before the date it is due.

C.19 General Record Keeping Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-6]

(a) Records of all required data, reports and support information shall be retained for a period of at least five (5) years from the date of monitoring sample, measurement, report, or application. These records shall be kept at the source location for a minimum of three (3) years. The records may be stored elsewhere for the remaining two (2) years as long as they are available upon request. If the Commissioner makes a request for records to the Permittee, the Permittee shall furnish the records to the Commissioner within a reasonable time.

(b) Unless otherwise specified in this permit, all record keeping requirements not already legally required shall be implemented within ninety (90) days of permit issuance.

C.20 General Reporting Requirements [326 IAC 2-7-5(3)(C)] [326 IAC 2-1.1-11]

(a) The source shall submit the attached Quarterly Deviation and Compliance Monitoring Report or its equivalent. Any deviation from permit requirements, the date(s) of each deviation, the cause of the deviation, and the response steps taken must be reported. This report shall be submitted within thirty (30) days of the end of the reporting period. The Quarterly Deviation and Compliance Monitoring Report shall include the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

(b) The report required in (a) of this condition and reports required by conditions in Section D of this permit shall be submitted to:

Indiana Department of Environmental Management
Compliance Data Section, Office of Air Quality
100 North Senate Avenue
Indianapolis, Indiana 46204

- (c) Unless otherwise specified in this permit, any notice, report, or other submission required by this permit shall be considered timely if the date postmarked on the envelope or certified mail receipt, or affixed by the shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAQ, on or before the date it is due.
- (d) Unless otherwise specified in this permit, all reports required in Section D of this permit shall be submitted within thirty (30) days of the end of the reporting period. All reports do require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).
- (e) The first report shall cover the period commencing on the date of issuance of this permit and ending on the last day of the reporting period. Reporting periods are based on calendar years.

Stratospheric Ozone Protection

C.21 Compliance with 40 CFR 82 and 326 IAC 22-1
Pursuant to 40 CFR 82 (Protection of Stratospheric Ozone), Subpart F, except as provided for motor vehicle air conditioners in Subpart B, the Permittee shall comply with the standards for recycling and emissions reduction:

- (a) Persons opening appliances for maintenance, service, repair, or disposal must comply with the required practices pursuant to 40 CFR 82.156.
- (b) Equipment used during the maintenance, service, repair, or disposal of appliances must comply with the standards for recycling and recovery equipment pursuant to 40 CFR 82.158.
- (c) Persons performing maintenance, service, repair, or disposal of appliances must be certified by an approved technician certification program pursuant to 40 CFR 82.161.

SECTION D.1

FACILITY OPERATION CONDITIONS

Facility Description [326 IAC 2-7-5(15)]:

- (a) Two (2) 20.9 MMBtu per hour natural gas-fired boilers equipped with low-NOx burners. These units were constructed in 2000.

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

Emission Limitations and Standards [326 IAC 2-7-5(1)]

D.1.1 Particulate Matter Limitation (PM) [326 IAC 6-2-4]

Pursuant to 326 IAC 6-2-4 (Particulate Matter Emission Limitations for Sources of Indirect Heating), the PM emissions from each 20.9 MMBtu per hour heat input boiler shall be limited to 0.4 pounds per MMBtu heat input.

This limitation is based on the following equation:

$$P_t = \frac{1.09}{Q^{0.26}}$$

Where: P_t = Pounds of particulate matter emitted per million Btu (lb/MMBtu) heat input; and
 Q = Total source maximum operating capacity rating in million Btu per hour (MMBtu/hr) heat input (Includes the two (2) 20.9 MMBtu/hr boilers, and the insignificant boilers: 3.6 MMBtu/hr boiler and 4.8 MMBtu/hr boiler.

D.1.2 Particulate Matter Limitation [326 IAC 12-1] [40 CFR 60, Subpart Dc]

Although this boiler is subject to 40 CFR 60, Subpart Dc (Standards of Performance for Small Industrial - Commercial - Institutional Steam Generating Units), there are no emission limitations applicable to this boiler, only record keeping requirements described in D.1.4.

D.1.3 Preventive Maintenance Plan [326 IAC 2-7-5(13)]

A Preventive Maintenance Plan, in accordance with Section B - Preventive Maintenance Plan, of this permit, is required for this facility.

Record Keeping and Reporting Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-19]

D.1.4 Record Keeping Requirements [326 IAC 12-1] [40 CFR 60, Subpart Dc]

- (a) To document compliance with Condition D.1.2, the Permittee shall maintain records in accordance with (1) through (2) below.

- (1) Calendar dates covered in the compliance determination period; and
- (2) Monthly fuel records.

The Permittee shall retain records of all recording/monitoring data and support information for a period of five (5) years, or longer if specified elsewhere in this permit, from the date of the monitoring sample, measurement, or report. Support information includes all calibration and maintenance records and all original strip-chart recordings for continuous monitoring instrumentation, and copies of all reports required by this permit.

- (b) All records shall be maintained in accordance with Section C - General Record Keeping Requirements, of this permit.

D.1.5 Reporting Requirements

- (a) A certification, signed by the responsible official, that certifies all of the fuels combusted during the period. The natural gas-fired boiler certification does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34);
- (b) The natural gas boiler certification shall be submitted to the address listed in Section C - General Reporting Requirements, of this permit, using the reporting forms located at the end of this permit, or their equivalent, within thirty (30) days after the end of the six (6) month period being reported.

SECTION D.2 FACILITY OPERATION CONDITIONS

Facility Description [326 IAC 2-7-5(15)]:

- (b) One (1) tablet manufacturing department, constructed in 1993, consisting of
 - (1) One (1) granulation department consisting of four (4) mixers, six (6) comminuting mills and four (4) steam-heated production ovens, equipped with a baghouse for particulate matter control, identified as EFDC1.
 - (2) One (1) tablet compression department consisting of one (1) granulator, and eleven (11) tablet presses, equipped with two (2) baghouses for particulate matter control, identified as V3 and V4.
 - (3) One (1) tablet coating department consisting of two (2) hi-coaters, equipped with two (2) baghouses for particulate mater control, identified as DC04 and DC05.
- (c) One (1) capsule manufacturing department, constructed in 1993, consisting of coating pans, auger feeders and several kettles, equipped with a baghouse for particulate matter control, identified as V5.
- (d) One (1) Phase IIIA production area, identified as emission unit EFDC2. This area manufactures several products, which involve tablet formulation, compression and filling of tablets, capsules and aqueous coating of tablets. This production area is rated at 1,960.3 pounds per batch (lbs/batch) of raw material and the PM emissions are controlled by baghouse EFDC2. The Phase IIIA production area uses 660 pounds per batch (lbs/batch) of ethanol in the coating process. The production area includes one (1) flo-coater for the application of sustained release coating, equipped with one (1) baghouses, identified as V7. These units were constructed in 2000.
- (e) Cleaning and sanitizing operations using isopropanol, bleaches, and non-solvent based sanitizing agents.

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

Emission Limitations and Standards [326 IAC 2-7-5(1)]

D.2.1 Particulate Matter (PM) [326 IAC 6-3-2]

Pursuant to 326 IAC 6-3-2 (Process Operations), the allowable PM emission rate from the tablet, capsule and phase IIIA manufacturing facilities shall not exceed the following PM emission limits:

Facility	Process Weight	PM Emission Limit (lbs/hour)
Tablet Manufacturing Department	26	0.23
Capsule Manufacturing Department	13.8	0.14
Phase IIIA Production Area	8.8	0.11

The pounds per hour limitation was calculated using the following equation:

Interpolation of the data for the process weight rate up to 60,000 pounds per hour shall be accomplished by use of the equation:

$$E = 4.10 P^{0.67}$$

where E = rate of emission in pounds per hour; and
P = process weight rate in tons per hour

D.2.2 Organic Solvents [326 IAC 8-1-6]

Pursuant to 326 IAC 8-1-6, the Best Available Control Technology (BACT) for the Control of volatile organic compounds shall be implemented and is as follows:

- (a) Process Modifications:
 - (1) For capsule manufacturing, the Permittee shall use flo-coaters for applying sustained release coatings for all products in which volatile organic compounds (VOCs) are used.
 - (2) The capture and offsite disposal of VOC containing chemicals; and
 - (3) Solvent handling procedures (currently being conducted):
 - (A) Solvents are stored in sealed 55-gallon drums until utilized in the manufacturing process.
 - (B) The drums are kept sealed except where solvents are withdrawn.
 - (C) The solvents are extracted from the drums using a dedicated pump.
 - (D) If one half of the drum content is needed, the entire drum can be transported to the manufacturing area for dispensing.
 - (E) If less than one half of the content of the drum is to be used, the needed portion is transported to the process area in a covered container.
 - (F) Where the manufacturing process requires other chemicals to be dissolved in liquid, the process is conducted in covered vessels.
 - (G) The use of isopropanol in cleaning and sanitizing operations shall be minimized by using bleaches and other non-solvent sanitizers where appropriate.
 - (4) The BACT shall be implemented such that:
 - (A) Implementation of the flo-coater shall reduce VOC emissions by 18%.
 - (B) The solvents shall be disposed offsite in accordance with the applicable hazardous waste rule found in 60 CFR Part 260 to Part 272, and shall reduce VOC emissions by 8%.
 - (C) The on-going solvent handling procedures shall reduce VOC emissions by 0.5%.
 - (D) The minimization of isopropanol in cleaning and sanitizing operations shall reduce VOC emissions by 8%.

The implementation of this BACT shall result in a total VOC reduction of 34.5% from 1995 VOC emission levels.

- (b) Condition 4 in CP 071-2389-00023, issued on February 3, 1993, has been superseded by the requirements specified in Condition D.2.2(a) of this permit.
- (c) Condition 6(a)(2) in CP 071-3874-00023, issued on January 25, 1995, has been superseded by the requirements specified in Condition D.2.2(a)(1) of this permit.
- (d) Condition 6(a)(1) in CP 071-3874-00023, issued on January 25, 1995, has been superseded by the requirements specified in Condition D.2.2(a)(3)(G) of this permit.

D.2.3 National Emission Standards for Pharmaceuticals Production [326 IAC 20-1][40 CFR 63, Subpart GGG]

Pursuant to 40 CFR 63.1251 (National Emission Standards for Pharmaceuticals Production), the source is subject to 40 CFR 63, Subpart GGG, however no control requirements apply because the source does not have any emission vents regulated by the rule. All vents have HAP concentrations in their vent stream less than 50 ppmv. Therefore, these vents are not considered "process vents" by the rule and are not regulated. Any changes to the process that would increase emissions from any individual vent to greater than 50 ppmv requires prior approval from IDEM, OAQ.

D.2.4 General Provisions Relating to NESHAPs [326 IAC 20-1] [40 CFR 63, Subpart A]

The provisions of 40 CFR 63, Subpart A - General Provisions, which are incorporated by reference in 326 IAC 20-1, apply to the facilities and operations described in this section except when otherwise specified in 40 CFR 63, Subpart GGG.

D.2.5 Preventive Maintenance Plan [326 IAC 2-7-5(13)]

A Preventive Maintenance Plan, in accordance with Section B - Preventive Maintenance Plan, of this permit, is required for these facilities and their control devices.

Compliance Determination Requirements

D.2.6 Particulate Matter (PM)

Pursuant to CP-071-238-00023, issued on February 3, 1993, CP071-3874-00023, issued on January 25, 1995, and Minor Source Modification 071-11653-00023, issued on April 20, 2000, and in order to comply with Condition D.2.1 the baghouses V2, V4, V5, V6, V7, V8, V9, and EU-2 for PM control shall be in operation and control emissions from the tablet, capsule, and Phase IIIA manufacturing facilities at all times these facilities are in operation.

D.2.7 National Emission Standards for Pharmaceuticals Production [326 IAC 20-1][40 CFR 63, Subpart GGG]

Pursuant to 40 CFR 63, Subpart GGG (National Emission Standards for Pharmaceuticals Production), HAP emissions from individual vents shall be determined using one of the following methods:

- (a) Process knowledge that indicates no HAP are present in the emission stream
- (b) Testing using Methods 18 of 40 CFR 63, Appendix A;
- (c) Testing using test methods validated according to the procedures in Method 301 of 40 CFR 60, of Appendix A; or
- (d) Engineering assessments as described in 40 CFR 63.1257(d)(2)(ii), which includes by is not limited to:

- (1) Previous test results, provided the tests are representative of current operating practices at the facility.
- (2) Bench-scale or pilot test data representative of the process under representative operating conditions.
- (3) Maximum flow rate, HAP emission rate, concentration, or other relevant parameter specified or implied within a permit limit applicable to the process vent.
- (4) Design analysis based on accepted chemical engineering principles, measurable process parameters, or physical or chemical laws or properties. Examples of analytical methods include, but are not limited to:
 - (i) Use of material balances based on process stoichiometry to estimate maximum organic HAP concentrations.
 - (ii) Estimation of maximum flow rate based on physical equipment design such as pump or blower capacities.
 - (iii) Estimation of HAP concentrations based on saturation conditions.
- (5) All data, assumptions, and procedures used in the engineering assessment shall be documented in accordance with 40 CFR 63.1260(e). Data or other information supporting a finding that the emissions estimation equations are inappropriate shall be reported in the precompliance report.

Compliance Monitoring Requirements [326 IAC 2-7-6(1)] [326 IAC 2-7-5(1)]

D.2.8 Visible Emissions Notations

- (a) Visible emission notations of the tablet, capsule and Phase IIIA manufacturing facility exhausts shall be performed once per shift during normal daylight operations when exhausting to the atmosphere. A trained employee shall record whether emissions are normal or abnormal.
- (b) For processes operated continuously, "normal" means those conditions prevailing, or expected to prevail, eighty percent (80%) of the time the process is in operation, not counting startup or shut down time.
- (c) In the case of batch or discontinuous operations, readings shall be taken during that part of the operation that would normally be expected to cause the greatest emissions.
- (d) A trained employee is an employee who has worked at the plant at least one (1) month and has been trained in the appearance and characteristics of normal visible emissions for that specific process.
- (e) The Compliance Response Plan for this unit shall contain troubleshooting contingency and response steps for when an abnormal emission is observed. Failure to take response steps in accordance with Section C - Compliance Monitoring Plan - Failure to Take Response Steps, shall be considered a violation of this permit.

D.2.9 Baghouse Inspections

Daily inspections shall be performed for the baghouses controlling the tablet, capsule, and phase IIIA manufacturing facilities. All defective bags shall be replaced. The daily inspection shall include the following:

- (a) Walk through the system and listen for proper operation.

- (b) Check for unusual occurrences in process.
- (c) Check compressed-air pressure.
- (d) Assure that dust is being removed from the system.

D.2.10 Broken or Failed Bag Detection

In the event that bag failure has been observed:

- (a) The affected compartments will be shut down immediately until the failed units have been repaired or replaced. Within eight (8) hours of the determination of failure, response steps according to the timetable described in the Compliance Response Plan shall be initiated. For any failure with corresponding response steps and timetable not described in the Compliance Response Plan, response steps shall be devised within eight (8) hours of discovery of the failure and shall include a timetable for completion. Operations may continue only if the event qualifies as an emergency and the Permittee satisfies the requirements of the emergency provisions of this permit (Section B - Emergency Provisions).
- (b) For single compartment baghouses, failed units and the associated process will be shut down immediately until the failed units have been repaired or replaced. Operations may continue only if the event qualifies as an emergency and the Permittee satisfies the requirements of the emergency provisions of this permit (Section B - Emergency Provisions).

Record Keeping and Reporting Requirement [326 IAC 2-7-5(3)] [326 IAC 2-7-19]

D.2.11 Record Keeping Requirements

- (a) To document compliance with Condition D.2.8, the Permittee shall maintain records of visible emission notations of the tablet, capsule and phase IIIA manufacturing facilities stack exhaust once per shift.
- (b) To document compliance with Condition D.2.9, the Permittee shall maintain records of the results of the inspections required under Condition D.2.9.
- (c) To document compliance with Condition D.2.2, the Permittee shall maintain monthly logs of information pertaining to the usage and handling of volatile organic solvents and the implementation of the flo-coaters.
- (d) To document compliance with Condition D.2.3 and D.2.7, the permittee shall keep records showing the HAP concentrations of all vent streams and the information necessary to support how the HAP concentrations were determined.
- (e) All records shall be maintained in accordance with Section C - General Record Keeping Requirements, of this permit.

D.2.12 Record Keeping Requirements for 40 CFR 63, Subpart GGG

Pursuant to 40 CFR 63, Subpart A and 40 CFR 63, Subpart GGG, the Permittee shall maintain the following records:

- (a) Copies of all records and reports required by 40 CFR 63, Subpart GGG.
- (b) Copies of the current and superceded versions of the Startup, Shutdown, and Malfunction plan.

- (c) Copies of startup, shutdown and malfunction records required under 40 CFR 63, Subpart GGG.

D.2.13 Reporting Requirements for 40 CFR 63, Subpart GGG

- (a) Pursuant to 40 CFR 63, Subpart A, the Permittee shall submit an initial notification to the Administrator immediately upon issuance of this permit. The initial notification shall contain:
 - (1) The name and address of the owner or operator;
 - (2) The address (i.e., physical location) of the emission units;
 - (3) An identification of the relevant standard, or other requirement, that is the basis of the notification and the date on which the source is required to be in compliance; and
 - (4) A statement indicating whether the source is a major source or an area source.
- (b) Pursuant to 40 CFR 63, Subpart GGG, the Permittee shall submit a Precompliance report at least 6 months prior to September 21, 2001. The Administrator shall have 90 days to approve or disapprove the plan. The plan shall be considered approved if the Administrator either approves or disapproves the plan in writing or fails to disapprove the plan in writing. If the request is denied, the Permittee must still be in compliance with the standard by the compliance date. The Precompliance report shall data and rationale used to support an engineering assessment to calculate uncontrolled emissions from process vents as required in 40 CFR 63.1257(d)(2)(ii).
- (c) Pursuant to 40 CFR 63.9, the Permittee shall submit a Notification of Compliance Status Report no later than 150 days after the compliance date. This report shall include:
 - (1) The results of any applicability determinations, emission calculations, or analyses used to identify and quantify HAP emissions from the affected source.
 - (2) The results of emissions profiles, performance tests, engineering analyses, design evaluations, or calculations used to demonstrate compliance. For performance tests, results should include descriptions of sampling and analysis procedures and quality assurance procedures.
 - (3) Descriptions of monitoring devices, monitoring frequencies, and the values of monitored parameters established during the initial compliance determinations, including data and calculations to support the levels established.
 - (4) Listing of all operating scenarios.
 - (5) Description of worst-case operating and /or testing conditions for control devices.
 - (6) Identification of emission points subject to overlapping requirements described in 40 CFR 63.1250(h) and the authority under which the Permittee will comply.
- (d) Pursuant to 40 CFR 63.1260(g), the Permittee shall submit Periodic Reports semiannually, beginning 60 operating days after the end of the applicable reporting period. The first report shall be submitted no later than 240 days after the date of Notification of Compliance Status is due and shall cover the 6-month period beginning on the date of Notification of Compliance Status is due.

- (e) Pursuant to 40 CFR 63.1260(h), the Permittee shall submit a quarterly report whenever a process change is made or a change in any of the information submitted in the Notification of Compliance Status Report. The report may be submitted as part of the next Periodic report required under 40 CFR 63.1260(g). The report shall include:
- (1) A brief description of the process change.
 - (2) A description of any modifications to the standard procedures or quality assurance procedures.
 - (3) Revisions to any of the information reported in the original Notification of Compliance Status Report.
 - (4) Information required by the Notification of Compliance Report under 40 CFR 63.1260(f).

SECTION D.3

FACILITY OPERATION CONDITIONS

Facility Description [326 IAC 2-7-5(15)]:

- (f) One (1) Colyte production area (identified as emission unit DC16-1), used to manufacture different types of Colyte, involving a dry mix blending operation, product container filling and labeling. This production area was constructed in 2000 and is rated at 3,956 pounds of raw material per batch (lbs/batch) and the PM emissions are controlled by baghouse DC16-1.

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

Emission Limitations and Standards [326 IAC 2-7-5(1)]

D.3.1 Particulate Matter (PM) [326 IAC 6-3-2]

Pursuant to 326 IAC 6-3-2 (Process Operations), the allowable PM emission rate from the colyte manufacturing department shall not exceed 0.187 pounds per hour when operating at a process weight rate of 20 pounds per hour. The pounds per hour limitation was calculated using the following equation:

Interpolation of the data for the process weight rate up to 60,000 pounds per hour shall be accomplished by use of the equation:

$$E = 4.10 P^{0.67}$$

where E = rate of emission in pounds per hour; and
P = process weight rate in tons per hour

Compliance Determination Requirements

D.3.2 Particulate Matter (PM)

Pursuant to Minor Source Modification CP-071-11653-00023, issued on April 20, 2000, and in order to comply with D.3.1, the baghouse EU-1 for PM control shall be in operation and control emissions from the colyte manufacturing facility at all times that the colyte manufacturing facility is in operation.

SECTION D.4 FACILITY OPERATION CONDITIONS

Facility Description [326 IAC 2-7-5(15)]: Insignificant Activities

- (a) Natural gas-fired combustion sources with heat input equal to or less than ten million (10,000,000) Btu per hour, constructed between 1985 and 2000, including:
 - (1) One (1) natural gas-fired boiler with maximum capacity of 4.8 MMBtu per hour [326 IAC 6-2-4];
 - (2) One (1) natural gas-fired boiler with maximum capacity of 3.6 MMBtu per hour [326 IAC 6-2-4]; and
- (b) The following equipment related to manufacturing activities not resulting in the emission of HAPs: brazing equipment, cutting torches, soldering equipment, welding equipment [326 IAC 6-3].
- (c) Paved and unpaved roads and parking lots with public access [326 IAC 6-4].
- (d) Other categories with emissions below insignificant thresholds:
 - (1) A liquid pharmaceutical manufacturing facility, consisting of liquid blending, filtration, and packaging, emitting less than three (3) pounds per hour of VOC.
 - (2) One (1) product weigh-up department for weighing the tablet, capsule, and liquid departments, consisting of six (6) weigh-up rooms with drums, scoops and scales, with emissions exhausted through one (1) baghouse for particulate matter control, identified as EFDC2. Particulate matter emissions before the baghouse are less than five (5) pounds per hour [326 IAC 6-3].

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

Emission Limitations and Standards [326 IAC 2-7-5(1)]

D.4.1 Particulate Matter (PM)

- (a) Pursuant to 326 IAC 6-2-4 (Emission Limitations for facilities specified in 326 IAC 6-2-1(d)), the particulate emissions from the 3.6 MMBtu/hour and 4.8 MMBtu/hour boilers shall be limited to 0.6 pounds per MMBtu heat input.

This limitation is based on the following equation:

$$P_t = \frac{1.09}{Q^{0.26}}$$

Where: P_t = Pounds of particulate matter emitted per million Btu (lb/MMBtu) heat input; and
 Q = Total source maximum operating capacity rating in million Btu per hour (MMBtu/hr) heat input (Includes the 4.8 MMBtu/hr boiler, and the 3.6 MMBtu/hr boiler).

D.4.2 Particulate Matter (PM) [326 IAC 6-3-2]

Pursuant to 326 IAC 6-3-2 (Process Operations), the allowable PM emission rate from the product weigh-up department and welding equipment shall not exceed the allowable PM emission rate based on the following equation:

Interpolation of the data for the process weight rate up to 60,000 pounds per hour shall be accomplished by use of the equation:

$$E = 4.10 P^{0.67} \quad \text{where}$$

E = rate of emission in pounds per hour; and
P = process weight rate in tons per hour

SECTION D.5 FACILITY OPERATION CONDITIONS

Facility Description [326 IAC 2-7-5(15)]:

- (g) One (1) Bupropion production line, to be constructed in 2005, with a maximum throughput rate of 270 batches per year and 2,400 pounds of dry solids per batch, consisting of the following:
- (1) One (1) granulation solution preparation process, consisting of the following:
 - (A) Two (2) mixers, each with a maximum capacity of 40 gallons.
 - (B) Two (2) mixers, each with a maximum capacity of 122 gallons.
 - (C) Alcohol storage drums.
 - (2) One (1) granulation and drying, screening, and blending process, using the existing baghouses V4 and V5 for particulate matter control, and exhausting to stacks EF -04 and EF-05. This process is consisted of the following:
 - (A) One (1) fluid bed dryer.
 - (B) One (1) Bohle bin, with a maximum capacity of 37 gallons.
 - (C) One (1) Bohle blender.
 - (3) One (1) tablet compression process.
 - (4) One (1) table coating preparation process.
 - (5) One (1) tablet coating process, consisted of three (3) spray guns, with a maximum throughput rate of 98,947 tablets per hour, controlled by one (1) regenerative thermal oxidizer, and exhausting to stack EF 11-2.
 - (6) One (1) tablet printing process.
 - (7) One (1) packaging process

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

Emission Limitations and Standards [326 IAC 2-7-5(1)]

D.5.1 VOC Emissions [326 IAC 8-1-6]

Pursuant to 326 IAC 8-1-6 (BACT), the Permittee shall control the VOC emissions from the tablet coating process with a Best Available Control Technology (BACT), which has been determined to be the following:

- (a) The VOC emissions from the tablet coating process of the Bupropion production line shall be controlled by a thermal oxidizer.
- (b) The control efficiency for thermal oxidizer shall be at least 98%.
- (c) The VOC emissions from thermal oxidizer shall not exceed 0.70 lbs/hr.

D.5.2 General Provisions Relating to NESHAPs [326 IAC 20-1] [40 CFR 63, Subpart A]

The provisions of 40 CFR 63, Subpart A - General Provisions, which are incorporated by reference in 326 IAC 20-1, apply to the facilities and operations described in this section except when otherwise specified in 40 CFR 63, Subpart GGG.

D.5.3 National Emission Standards for Pharmaceuticals Production [326 IAC 20-1][40 CFR 63, Subpart GGG]

The Bupropion production line is subject to the requirements of 40 CFR 63, Subpart GGG and the Permittee shall comply with the following applicable requirements:

- (a) Pursuant to 40 CFR 63.1254(c), the process vents of the tablet coating process shall route to a combustion control device achieving an outlet TOC concentration, as calibrated on methane or the predominant HAP, of 20 ppmv or less, and an outlet concentration of hydrogen halides and halogens of 20 ppmv or less.
- (b) The control device (thermal oxidizer) of the tablet coating process shall comply with the equipment leak standards specified in 40 CFR 63.1255.

D.5.4 Particulate Matter (PM) [326 IAC 6-3-2]

Particulate emissions from each of the granulation and drying, screening, and blending processes shall not exceed to 0.64 lbs/hr when the process weight rate is 126 lbs/hr.

The pounds per hour limitation was calculated with the following equation:

Interpolation of the data for the process weight rate up to sixty thousand (60,000) pounds per hour shall be accomplished by use of the equation:

$$E = 4.10 P^{0.67} \quad \text{where } E = \text{rate of emission in pounds per hour and} \\ P = \text{process weight rate in tons per hour}$$

D.5.5 Preventive Maintenance Plan [326 IAC 2-7-5(13)]

A Preventive Maintenance Plan, in accordance with Section B - Preventive Maintenance Plan, of this permit, is required for these facilities and their control devices.

Compliance Determination Requirements

D.5.6 VOC Control

In order to comply with Conditions D.5.1 and D.5.3, the regenerative thermal oxidizer shall be in operation and control emissions from the tablet coating process at all times that this process is in operation.

D.5.7 Particulate Matter (PM)

In order to comply with Condition D.5.4, the baghouses V4 and V5 for PM control shall be in operation and control emissions from the granulation and drying, screening, and blending processes at all times that these facilities are in operation.

D.5.8 Testing Requirements [326 IAC 2-7-6(1),(6)] [326 IAC 2-1.1-11] [326 IAC 8-1-6]

In order to demonstrate compliance with Condition D.5.1, the Permittee shall perform VOC (including emission rate and capture and destruction efficiency) testing for the thermal oxidizer equipped with the tablet coating process, within 60 days after achieving the maximum production, but not later than 180 days after initial startup, utilizing methods as approved by the Commissioner. This test shall be repeated at least once every five (5) years from the date of this

valid compliance demonstration. Testing shall be conducted in accordance with Section C - Performance Testing.

D.5.9 National Emission Standards for Pharmaceuticals Production [326 IAC 20-1][40 CFR 63, Subpart GGG]

Pursuant to 40 CFR 63.1257(a)(5), to demonstrate initial compliance with the alternative standard in 40 CFR 63.1254(c) and Condition D.5.3(a), the Permittee shall be in compliance with the monitoring provisions in 40 CFR 63.1258(b)(5) upon the start-up of Bupropion production line. The Permittee shall use Method 18 to determine the predominant organic HAP in the emission stream if the TOC monitor is calibrated on the predominant HAP.

Compliance Monitoring Requirements [326 IAC 2-7-6(1)] [326 IAC 2-7-5(1)]

D.5.10 Continuous Emissions Monitoring [326 IAC 20-1] [40 CFR 63, Subpart GGG] [326 IAC 3-5-2]

Pursuant to 40 CFR 63.1258(b)(5), the Permittee shall monitor and record the outlet TOC concentration and the outlet hydrogen halide and halogen concentration every 15 minutes during the period in which the device is functioning in achieving the HAP removal required by 40 CFR 63, Subpart GGG using CEMS as specified in 40 CFR 63.1258 (b)(5)(i)(A) through (D) and 326 IAC 3-5-2. The requirements of 326 IAC 3-5 is not federally enforceable.

D.5.11 Visible Emissions Notations

- (a) Visible emission notations of the granulation and drying, screening, and blending processes exhausts shall be performed once per shift during normal daylight operations when exhausting to the atmosphere. A trained employee shall record whether emissions are normal or abnormal.
- (b) For processes operated continuously, "normal" means those conditions prevailing, or expected to prevail, eighty percent (80%) of the time the process is in operation, not counting startup or shut down time.
- (c) In the case of batch or discontinuous operations, readings shall be taken during that part of the operation that would normally be expected to cause the greatest emissions.
- (d) A trained employee is an employee who has worked at the plant at least one (1) month and has been trained in the appearance and characteristics of normal visible emissions for that specific process.
- (e) The Compliance Response Plan for this unit shall contain troubleshooting contingency and response steps for when an abnormal emission is observed. Failure to take response steps in accordance with Section C - Compliance Response Plan - Preparation, Implementation, Records and Reports shall be considered a deviation from this permit.

D.5.12 Thermal Oxidizer Temperature

- (a) A continuous monitoring system shall be calibrated, maintained, and operated on the thermal oxidizer for measuring operating temperature. For the purpose of this condition, continuous means no less than once per minute. The output of this system shall be recorded as an hourly average. From the date of issuance of this permit until the approved stack test results are available, the Permittee shall operate the thermal oxidizer at or above the hourly average temperature of 1,500°F.
- (b) The Permittee shall determine the hourly average temperature from the most recent valid stack test that demonstrates compliance with limits in conditions D.5.1 and D.5.3, as approved by IDEM.

- (c) On and after the date the approved stack test results are available, the Permittee shall operate the thermal oxidizer at or above the hourly average temperature as observed during the compliant stack test.

D.5.13 Parametric Monitoring

- (a) The Permittee shall determine the appropriate duct pressure or fan amperage from the most recent valid stack test that demonstrates compliance with limits in Conditions D.5.1 and D.5.3, as approved by IDEM.
- (b) The duct pressure or fan amperage shall be observed at least once per day when the thermal oxidizer is in operation. On and after the date the approved stack test results are available, the duct pressure or fan amperage shall be maintained within the normal range as established in most recent compliant stack test.

D.5.14 Baghouse Inspections

Daily inspections shall be performed for the baghouses controlling the granulation and drying, screening, and blending processes. All defective bags shall be replaced. The daily inspection shall include the following:

- (a) Walk through the system and listen for proper operation.
- (b) Check for unusual occurrences in process.
- (c) Check compressed-air pressure.
- (d) Assure that dust is being removed from the system.

D.5.15 Broken or Failed Bag Detection

In the event that bag failure has been observed:

- (a) For multi-compartment units, the affected compartments will be shut down immediately until the failed units have been repaired or replaced. Within eight (8) business hours of the determination of failure, response steps according to the timetable described in the Compliance Response Plan shall be initiated. For any failure with corresponding response steps and timetable not described in the Compliance Response Plan, response steps shall be devised within eight (8) business hours of discovery of the failure and shall include a timetable for completion. Failure to take response steps in accordance with Section C - Compliance Response Plan -Preparation, Implementation, Records, and Reports, shall be considered a deviation from this permit. If operations continue after bag failure is observed and it will be 10 days or more after the failure is observed before the failed units will be repaired or replaced, the Permittee shall promptly notify the IDEM, OAQ of the expected date the failed units will be repaired or replaced. The notification shall also include the status of the applicable compliance monitoring parameters with respect to normal, and the results of any response actions taken up to the time of notification.
- (b) For single compartment baghouses, if failure is indicated by a significant drop in the baghouse's pressure readings with abnormal visible emissions or the failure is indicated by an opacity violation, or if bag failure is determined by other means, such as gas temperatures, flow rates, air infiltration, leaks, dust traces or triboflows, then failed units and the associated process will be shut down immediately until the failed units have been repaired or replaced. Operations may continue only if the event qualifies as an

emergency and the Permittee satisfies the requirements of the emergency provisions of this permit (Section B - Emergency Provisions).

Record Keeping and Reporting Requirement [326 IAC 2-7-5(3)] [326 IAC 2-7-19]

D.5.16 Record Keeping Requirements

- (a) To document compliance with Condition D.5.10, the Permittee shall maintain records of the CEM data for the outlet TOC concentration, and the outlet hydrogen halide and halogen concentration.
- (b) To document compliance with Condition D.5.11, the Permittee shall maintain records of visible emission notations of the granulation and drying, screening, and blending processes stack exhausts once per shift.
- (c) To document compliance with Condition D.5.12, the Permittee shall maintain continuous temperature records for the thermal oxidizer and the 3-hour average temperature used to demonstrate compliance during the most recent compliant stack test.
- (d) To document compliance with Condition D.5.13, the Permittee shall maintain daily records of the duct pressure or fan amperage for the thermal oxidizer/heat recovery steam generator.
- (e) To document compliance with Conditions D.5.14, the Permittee shall maintain records of the results of the inspections required under Condition D.5.14.
- (f) To document compliance with Condition D.5.5, the Permittee shall maintain records of any additional inspections prescribed by the Preventive Maintenance Plan.
- (g) All records shall be maintained in accordance with Section C - General Record Keeping Requirements, of this permit.

D.5.17 Record Keeping Requirements for 40 CFR 63, Subpart GGG [40 CFR 63.1259]

Pursuant to 40 CFR 63.1259, the Permittee shall keep the following records:

- (a) The record keeping requirements in 40 CFR 63, Subpart A.
- (b) Records of equipment operations.
- (c) Operating scenarios.
- (d) Equipment leak detection and repair programs.
- (e) Records of inspections.

D.5.18 Reporting Requirements for 40 CFR 63, Subpart GGG [40 CFR 63.1260]

Pursuant to 40 CFR 63.1260, the Permittee shall comply with the following reporting requirements:

- (a) Initial notification in accordance with 40 CFR 63.9(b) or (d)
- (b) Notification of CMS performance evaluation as specified in 40 CFR 63.1259(d).
- (c) Notification of compliance status report as specified in 40 CFR 63.1259(f).
- (e) Periodic reports as specified in 40 CFR 63.1259(g).

- (f) Notification of process change.
- (i) Reports of startup, shut down, and malfunction.

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT OFFICE OF AIR QUALITY

PART 70 OPERATING PERMIT CERTIFICATION

Source Name: Schwarz Pharma Manufacturing, Inc.
Source Address: 1101 C Avenue West, Seymour, Indiana 47274
Mailing Address: 1101C Avenue West, Seymour, Indiana 47274
Part 70 Permit No.: 071-7162-00023

This certification shall be included when submitting monitoring, testing reports/results or other documents as required by this permit.

Please check what document is being certified:

- Annual Compliance Certification Letter
- Test Result (specify)
- Report (specify)
- Notification (specify)
- Affidavit (specify)
- Other (specify)

I certify that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.

Signature:

Printed Name:

Title/Position:

Phone:

Date:

**INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY
COMPLIANCE BRANCH
100 North Senate Avenue
Indianapolis, Indiana 46204
Phone: 317-233-5674
Fax: 317-233-5967**

**PART 70 OPERATING PERMIT
EMERGENCY OCCURRENCE REPORT**

Source Name: Schwarz Pharma Manufacturing, Inc.
Source Address: 1101 C Avenue West, Seymour, Indiana 47274
Mailing Address: 1101 C Avenue West, Seymour, Indiana 47274
Part 70 Permit No.: 071-7162-00023

This form consists of 2 pages

Page 1 of 2

- This is an emergency as defined in 326 IAC 2-7-1(12)
- The Permittee must notify the Office of Air Quality (OAQ), within four (4) business hours (1-800-451-6027 or 317-233-5674, ask for Compliance Section); and
 - The Permittee must submit notice in writing or by facsimile within two (2) days (Facsimile Number: 317-233-5967), and follow the other requirements of 326 IAC 2-7-16.

If any of the following are not applicable, mark N/A

Facility/Equipment/Operation:

Control Equipment:

Permit Condition or Operation Limitation in Permit:

Description of the Emergency:

Describe the cause of the Emergency:

If any of the following are not applicable, mark N/A

Page 2 of 2

Date/Time Emergency started:
Date/Time Emergency was corrected:
Was the facility being properly operated at the time of the emergency? Y N Describe:
Type of Pollutants Emitted: TSP, PM-10, SO ₂ , VOC, NO _x , CO, Pb, other:
Estimated amount of pollutant(s) emitted during emergency:
Describe the steps taken to mitigate the problem:
Describe the corrective actions/response steps taken:
Describe the measures taken to minimize emissions:
If applicable, describe the reasons why continued operation of the facilities are necessary to prevent imminent injury to persons, severe damage to equipment, substantial loss of capital investment, or loss of product or raw materials of substantial economic value:

Form Completed by:

Title / Position:

Date:

Phone:

A certification is not required for this report.

**INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY
COMPLIANCE DATA SECTION**

**PART 70 OPERATING PERMIT
SEMI-ANNUAL NATURAL GAS FIRED BOILER CERTIFICATION**

Source Name: Schwarz Pharma Manufacturing, Inc.
Source Address: 1101 C Avenue West, Seymour, Indiana 47274
Mailing Address: 1101 C Avenue West, Seymour, Indiana 47274
Part 70 Permit No.: 071-7162-00023

<input type="checkbox"/> Natural Gas Only <input type="checkbox"/> Alternate Fuel burned From: _____ To: _____
--

I certify that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.
Signature: _____
Printed Name: _____
Title/Position: _____
Phone: _____
Date: _____

A certification by the responsible official as defined by 326 IAC 2-7-1(34) is required for this report.

**INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY
COMPLIANCE DATA SECTION**

**PART 70 OPERATING PERMIT
QUARTERLY DEVIATION AND COMPLIANCE MONITORING REPORT**

Source Name: Schwarz Pharma Manufacturing, Inc.
Source Address: 1101 C Avenue West, Seymour, Indiana 47274
Mailing Address: 1101 C Avenue West, Seymour, Indiana 47274
Part 70 Permit No.: 071-7162-00023

Months: _____ to _____ Year: _____

Page 1 of 2

This report is an affirmation that the source has met all the requirements stated in this permit. This report shall be submitted quarterly based on a calendar year. Any deviation from the requirements, the date(s) of each deviation, the probable cause of the deviation, and the response steps taken must be reported. Deviations that are required to be reported by an applicable requirement shall be reported according to the schedule stated in the applicable requirement and do not need to be included in this report. Additional pages may be attached if necessary. If no deviations occurred, please specify in the box marked "No deviations occurred this reporting period".

NO DEVIATIONS OCCURRED THIS REPORTING PERIOD.

THE FOLLOWING DEVIATIONS OCCURRED THIS REPORTING PERIOD

Permit Requirement (specify permit condition #)

Date of Deviation:

Duration of Deviation:

Number of Deviations:

Probable Cause of Deviation:

Response Steps Taken:

Permit Requirement (specify permit condition #)

Date of Deviation:

Duration of Deviation:

Number of Deviations:

Probable Cause of Deviation:

Response Steps Taken:

Permit Requirement (specify permit condition #)	
Date of Deviation:	Duration of Deviation:
Number of Deviations:	
Probable Cause of Deviation:	
Response Steps Taken:	
Permit Requirement (specify permit condition #)	
Date of Deviation:	Duration of Deviation:
Number of Deviations:	
Probable Cause of Deviation:	
Response Steps Taken:	
Permit Requirement (specify permit condition #)	
Date of Deviation:	Duration of Deviation:
Number of Deviations:	
Probable Cause of Deviation:	
Response Steps Taken:	

Form Completed By:

Title/Position:

Date:

Phone:

Attach a signed certification to complete this report.

Indiana Department of Environmental Management Office of Air Quality

Technical Support Document (TSD) for a Part 70 Significant Source Modification and a Part 70 Significant Permit Modification

Source Background and Description

Source Name:	Schwarz Pharma Manufacturing
Source Location:	1101 C Avenue West, Seymour, Indiana 47274
County:	Jackson
SIC Code:	2834
Operation Permit No.:	T071-7162-00023
Operation Permit Issuance Date:	March 25, 2002
Significant Source Modification No.:	T071-18489-00023
Significant Permit Modification No.:	T071-18639-00023
Permit Reviewer:	ERG/YC

The Office of Air Quality (OAQ) has reviewed a modification application from Schwarz Pharma Manufacturing, Inc. relating to the construction and operation of the following emission units:

- (g) One (1) Bupropion production line, to be constructed in 2005, with a maximum throughput rate of 270 batches per year and 2,400 pounds of dry solids per batch, consisting of the following:
- (1) One (1) granulation solution preparation process, consisting of the following:
 - (A) Two (2) mixers, each with a maximum capacity of 40 gallons.
 - (B) Two (2) mixers, each with a maximum capacity of 122 gallons.
 - (C) Alcohol storage drums.
 - (2) One (1) granulation and drying, screening, and blending process, using the existing baghouses V4 and V5 for particulate matter control, and exhausting to stacks EF-04 and EF-05. This process consists of the following:
 - (A) One (1) fluid bed dryer.
 - (B) One (1) Bohle bin, with a maximum capacity of 37 gallons.
 - (C) One (1) Bohle blender.
 - (3) One (1) tablet compression process.
 - (4) One (1) tablet coating preparation process.
 - (5) One (1) tablet coating process, consisting of three (3) spray guns, with a

maximum throughput rate of 98,947 tablets per hour, controlled by one (1) regenerative thermal oxidizer, and exhausting to stack EF 11-2.

- (6) One (1) tablet printing process.
- (7) One (1) packaging process

History

On December 12, 2003, Schwarz Pharma Manufacturing, Inc. submitted an application to the OAQ requesting to construct and operate a Bupropion production line. This new line will be equipped with a thermal oxidizer for VOC control. Schwarz Pharma Manufacturing, Inc. is an existing pharmaceutical manufacturing plant and their Part 70 permit (T071-7162-00023) was issued on March 25, 2002.

On October 21, 2004, the Permittee requested a revision to the pressure drop monitoring conditions for the existing baghouses. The Permittee stated that pressure drop is not a good indicator for the operation of the baghouses at this source because the air flow rates are not constant. The Permittee stated that they often adjust the fan speeds depending on the manufacturing process (batch processes). The Permittee stated that they designed the dust collectors based on the maximum fan speed of each manufacturing process. However, this plant is operating at a flow rate much lower than the maximum fan speeds. When the manufacturing process is down, the fan speed is low. This results in pressure drop readings lower than 1.0 inches of water. In addition, there is not much dust collect in the filters, which also results in low pressure drop readings.

Therefore, low pressure drop readings do not necessarily mean that there are leaks in the baghouses. The Permittee proposed the following alternative monitoring conditions for the baghouses at this source:

- (a) Daily visible emission notations.
- (b) Daily inspections for the dust collectors, including the following:
 - (1) Walk through the system and listen for proper operation.
 - (2) Check for unusual occurrences in process.
 - (3) Check compressed-air pressure.
 - (4) Assure that dust is being removed from the system.

Since the pressure drop reading is not a good indicator for the dust collectors operating at this source, IDEM, OAQ agrees that the Permittee can comply with the proposed alternative monitoring conditions, instead of monitoring pressure drop of the baghouses, to ensure proper operation of all the existing baghouses.

In the e-mail received on April 15, 2005, the Permittee also requested the following changes to the unit description of the existing units:

- (a) For the existing table manufacturing department:
 - (1) The production ovens equipped with the granulation department are steam heated ovens, not electric ones.
 - (2) The baghouse equipped in conjunction with the granulation department is identified as EFDC1.

- (3) The tablet compression department is controlled by two (2) baghouses, identified as V3 and V4.
- (4) The baghouses equipped in conjunction with the tablet coating department are identified DC04 and DC05.
- (b) For the existing Phase IIA production area:
 - (1) The identification number for this production area is EFDC2.
 - (2) The baghouse equipped in conjunction with the Phase IIA production area is identified as EFDC2
 - (3) The flo-coater at this area is equipped with one (1) baghouse, identified as baghouse V7.
- (c) For the existing Colyte production area:
 - (1) The identification number for this production area is DC16-1.
 - (2) The baghouse equipped in conjunction with this production area is identified as DC16-1.

The above changes will not affect the potential to emit of the existing emission units or trigger new applicable requirements. Therefore, these changes will be incorporated into the revised Part 70 permit.

Upon further review, IDEM, OAQ has made the following changes to the permit:

- (a) In accordance with the credible evidence rule (62 Fed. Reg. 8314, Feb 24, 1997); Section 113(a) of the Clean Air Act, 42 U.S. C. § 7413 (a); and a letter from the United States Environmental Protection Agency (USEPA) to IDEM, OAQ dated May 18, 2004, all permits must address the use of credible evidence; otherwise, U.S. EPA will object to the permits. A new condition - B.25 has been incorporated into the revised permit to address credible evidence.
- (b) The mailing address of IDEM, OAQ has been changed as follows:

110 North Senate Avenue
Indianapolis, Indiana 46204

This change has been made throughout the whole permit.

Enforcement Issue

There are no enforcement actions pending.

Stack Summary

Stack ID	Operation	Height (feet)	Diameter (feet)	Flow Rate (acfm)	Temperature (°F)
EF 11-2	RTO	40	1.0	900	225

Recommendation

The staff recommends to the Commissioner that the Part 70 Significant Source Modification and the Part 70 Significant Permit Modification be approved. This recommendation is based on the following facts and conditions:

Unless otherwise stated, information used in this review was derived from the application and additional information submitted by the applicant.

An application for the purposes of this review was received on December 12, 2003. Additional information was received on November 8, 2004, November 11, 2004, February 14, 2005, April 15, 2005, May 5, 2005, and May 17, 2005.

Emission Calculations

See Appendix A of this document for detailed emissions calculations (pages 1 through 4).

Potential To Emit of Modification

Pursuant to 326 IAC 2-1.1-1(16), Potential to Emit is defined as “the maximum capacity of a stationary source to emit any air pollutant under its physical and operational design. Any physical or operational limitation on the capacity of a source to emit an air pollutant, including air pollution control equipment and restrictions on hours of operation or type or amount of material combusted, stored, or processed shall be treated as part of its design if the limitation is enforceable by the U. S. EPA.”

This table reflects the PTE before controls. Control equipment is not considered federally enforceable until it has been required in a federally enforceable permit.

Pollutant	Potential To Emit (tons/year)
PM	435
PM-10	435
SO ₂	Negligible
VOC	151
CO	0.08
NO _x	0.10

HAPs	Potential To Emit (tons/year)
Methanol	7.17
TOTAL	7.17

Justification for Modification

This modification is being performed through a Part 70 Significant Source Modification because the potential to emit PM, PM10, and VOC is each greater than 25 tons per year, pursuant to 326 IAC 2-7-10.5(f)(4). The permit modification is being performed through a Significant Permit Modification pursuant to 326 IAC 2-7-12(d) because this is a modification under provisions of the Title I of CAA, and involves significant changes to existing monitoring requirements in the Part 70 permit.

County Attainment Status

The source is located in Jackson County.

Pollutant	Status
PM-10	Attainment
PM 2.5	Attainment or Unclassifiable
SO ₂	Attainment
NO ₂	Attainment
1- hour Ozone	Attainment
8- hour Ozone	Nonattainment

CO	Attainment
Lead	Attainment

- (a) Volatile organic compounds (VOC) and Nitrogen Oxides (NOx) are regulated under the Clean Air Act (CAA) for the purposes of attaining and maintaining the National Ambient Air Quality Standards (NAAQS) for ozone. Therefore, VOC and NOx emissions are considered when evaluating the rule applicability relating to the ozone standards. Jackson County has been designated as nonattainment for the 8-hour ozone standard. Therefore, VOC and NOx emissions were reviewed pursuant to the requirements for Emission Offset and 326 IAC 2-3.
- (b) Jackson County has been classified as unclassifiable or attainment for PM 2.5. U.S. EPA has not yet established the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2 for PM 2.5 emissions. Therefore, until the U.S. EPA adopts specific provisions for PSD review for PM 2.5 emissions, it has directed states to regulate PM10 emissions as surrogate for PM 2.5 emissions.
- (c) Jackson County has been classified as attainment or unclassifiable in Indiana for all other criteria pollutants. Therefore, these emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2.
- (d) Fugitive Emissions
 Since this type of operation is not in one of the 28 listed source categories under 326 IAC 2-2 and 326 IAC 2-3 and since there are no applicable New Source Performance Standards that were in effect on August 7, 1980, the fugitive PM emissions are not counted toward determination of PSD and Emission Offset applicability.

Source Status

Existing Source PSD and Emission Offset Definition (emissions after controls, based upon 8760 hours of operation per year at rated capacity and/or as otherwise limited):

Pollutant	Emissions (tons/year)
PM	1.45
PM-10	1.45
SO ₂	0.20
VOC	142
CO	15.0
NO _x	8.80

- (a) This existing source is an Emission Offset major stationary source because an nonattainment regulated pollutant (VOC) is emitted at a rate of 100 tons per year or more, and it is not in one of the 28 listed source categories.
- (b) This existing source is not a PSD major stationary source because no attainment regulated pollutant is emitted at a rate of 250 tons per year or more, and it is not in one of the 28 listed source categories.
- (c) These emissions are from the Technical Support Document (TSD) for the Permittee's Part 70 Permit (T071-7162-00023), issued on March 25, 2002.

Potential to Emit of Modification After Issuance

The table below summarizes the potential to emit, reflecting all limits, of the significant emission units after controls. The control equipment is considered federally enforceable only after issuance of this Part 70 source modification.

Process/facility	Potential to Emit (tons/year)						
	PM	PM-10	SO ₂	VOC	CO	NO _x	HAPs
Coating Process of the New Bupropion Production Line	0.13	0.13	-	Less than 3.07	-	-	Less than 0.14
Granulation, Drying, Screening, and Blending Processes of the New Bupropion Production Line	Less than 0.44	Less than 0.44	-	-	-	-	-
NG Combustion from RTO	0.01	0.01	Negligible	0.01	0.08	0.10	Negligible
PTE of this Modification	Less than 0.58	Less than 0.58	Negligible	Less than 3.08	0.08	0.10	Less than 0.14
PSD and Emission Offset Significant Thresholds	250	250	250	40	250	40	NA

* This is from the TSD for T071-7162-00023, issued on March 25, 2002.

- (a) This modification to an existing Emission Offset major source is not major because the potential to emit of this modification is less than the significant thresholds of 40 tons/yr for VOC and NOx. Therefore, the requirements of 326 IAC 2-3 (Emission Offset) are not applicable.
- (b) This modification to an existing PSD minor source is not major because the potential to emit of this modification is less than the PSD significant thresholds. Therefore, the requirements of 326 IAC 2-2 (PSD) are not applicable.

Federal Rule Applicability

- (a) There are no New Source Performance Standards (NSPS)(326 IAC 12 and 40 CFR Part 60) applicable to this proposed modification.
- (b) This existing pharmaceutical manufacturing plant is a HAP major source and is subject to the National Emission Standards for Hazardous Air Pollutants for Pharmaceuticals Production (40 CFR 63.1250 - 63.1261, Subpart GGG).

The new Bupropion production line will be constructed after April 2, 1997 and will be controlled by a thermal oxidizer. However, the installation of this new line is not considered reconstruction of the existing source and the potential to emit HAP from this new production line is less than 10 tons/yr for a single HAP and less than 25 tons/yr for total HAPs before control. Therefore, this new production line is not considered a new affected source under 40 CFR 63, Subpart GGG, pursuant to 40 CFR 63.1250(b). This new production line is subject to the following requirements for existing sources in 40 CFR 63, Subpart GGG:

Emission Standards

- (a) The Permittee elected to comply with the alternative standard in 40 CFR 63.1254(c) for the process vents of the new Bupropion production line, which

states that compliance with the process vent standards can be demonstrated by routing vents from a process to a combustion control device achieving an outlet TOC concentration, as calibrated on methane or the predominant HAP, of 20 ppmv or less, and an outlet concentration of hydrogen halides and halogens of 20 ppmv or less.

- (b) The control device (thermal oxidizer) of the new Bupropion production line shall comply with the equipment leak standards specified in 40 CFR 63.1255.

Compliance Demonstration

Pursuant to 40 CFR 63.1257(a)(5), to demonstrate initial compliance with the alternative standard in 40 CFR 63.1254(c), the Permittee shall be in compliance with the monitoring provisions in 40 CFR 63.1258(b)(5) upon the start-up of Bupropion production line. The Permittee shall use Method 18 to determine the predominant organic HAP in the emission stream if the TOC monitor is calibrated on the predominant HAP.

Compliance Monitoring

Pursuant to 40 CFR 63.1258(b)(5), the Permittee shall monitor and record the outlet TOC concentration and the outlet hydrogen halide and halogen concentration every 15 minutes during the period in which the device is functioning in achieving the HAP removal required by 40 CFR 63, Subpart GGG using CEMS as specified in 40 CFR 63.1258 (b)(5)(i)(A) through (D).

Recordkeeping and Reporting

The Permittee shall comply with the recordkeeping requirements in 40 CFR 63.1259 and the reporting requirements in 40 CFR 63.1260.

- (c) This modification does involve a pollutant-specific emissions unit (the coating process) as defined in 40 CFR 64.1:
- (1) With the potential to emit before controls equal to or greater than the major source threshold;
 - (2) That is subject to an emission limitation or standard; and
 - (3) Uses a control device (a thermal oxidizer) as defined in 40 CFR 64.1 to comply with that emission limitation or standard.

Therefore, the requirements of 40 CFR 64 (Compliance Assurance Monitoring) are applicable to this modification. However, since the coating process is part of the new Bupropion production line, which is subject to the requirements of NESHAP, Subpart GGG, the CAM requirements are exempt for this coating process, pursuant to 40 CFR 64.2(b)(1).

State Rule Applicability - Bupropion Production Line

326 IAC 2-4.1 (New Sources of Hazardous Air Pollutants)

The potential to emit HAP of this modification is less than 10 tons/yr for a single HAP and less than 25 tons/yr for any combination HAPs. Therefore, the requirements of 326 IAC 2-4.1 are not applicable.

326 IAC 5-1 (Opacity Limitations)

Pursuant to 326 IAC 5-1-2 (Opacity Limitations), except as provided in 326 IAC 5-1-3 (Temporary Alternative Opacity Limitations), opacity shall meet the following, unless otherwise stated in the permit:

- (a) Opacity shall not exceed an average of forty percent (40%) in any one (1) six (6) minute averaging period as determined in 326 IAC 5-1-4.
- (b) Opacity shall not exceed sixty percent (60%) for more than a cumulative total of fifteen (15) minutes (sixty (60) readings as measured according to 40 CFR 60, Appendix A, Method 9 or fifteen (15) one (1) minute nonoverlapping integrated averages for a continuous opacity monitor) in a six (6) hour period.

326 IAC 8-5-2 (Synthesized Pharmaceutical Manufacturing Operations)

The new Bupropion production line is not subject to the requirements of 326 IAC 8-5-2 (Synthesized Pharmaceutical Manufacturing Operations) because no chemical synthesis occurs at this production line.

326 IAC 8-1-6 (General Reduction Requirements for VOC Emissions)

The potential VOC emissions from the tablet coating process of the new Bupropion production line are greater than 25 tons/yr and there are no other applicable requirements in 326 IAC 8 that apply to this pharmaceutical production line. Therefore, the tablet coating process of this new line is subject to the requirements of 326 IAC 8-1-6 and is required to control the VOC emissions with Best Available Control Technology (BACT). According to the BACT analysis submitted by the Permittee on December 12, 2003, the for similar sources is the use of a thermal oxidizer with a control efficiency of 98%. The Permittee has elected to install a regenerative thermal oxidizer with 98% control to control the VOC emissions from the tablet coating process of this new Bupropion production line. IDEM, OAQ has determined that the BACT for this tablet coating process is as follows:

- (a) The VOC emissions from the tablet coating process of the Bupropion production line shall be controlled by a thermal oxidizer.
- (b) The destruction efficiency for thermal oxidizer shall be at least 98%.
- (c) The capture efficiency shall be 100% as defined in EPA Method 204.
- (d) The VOC emissions from thermal oxidizer shall not exceed 0.70 lbs/hr, which is equivalent to 3.07 tons/yr of VOC emissions.

326 IAC 6-3-2 (Particulate Emission Limitations for Manufacturing Processes)

Particulate emissions from each of the granulation and drying, screening, and blending processes shall not exceed 0.64 lbs/hr when the process weight rate is 2,400 (lbs/batch) / 19 (hrs/batch) = 126 lbs/hr.

The pounds per hour limitation was calculated with the following equation:

Interpolation of the data for the process weight rate up to sixty thousand (60,000) pounds per hour shall be accomplished by use of the equation:

$$E = 4.10 P^{0.67} \quad \text{where } E = \text{rate of emission in pounds per hour and} \\ P = \text{process weight rate in tons per hour}$$

According to the emission calculations (see Appendix A), the potential to emit PM after control from the granulation and drying, screening, and blending processes is less than the limit above. The use of baghouses V4 and V5 ensures compliance with the above particulate emission limit.

Testing Requirements

In order to comply with the BACT limits for the tablet coating process, which will be controlled by a thermal oxidizer, the Permittee shall perform VOC (including emission rate and destruction efficiency) testing for the thermal oxidizer equipped with the tablet coating process, within 60 days

after achieving the maximum production, but not later than 180 days after initial startup, utilizing methods as approved by the Commissioner. This test shall be repeated at least once every five (5) years from the date of this valid compliance demonstration. Testing shall be conducted in accordance with Section C - Performance Testing.

Compliance Requirements

Permits issued under 326 IAC 2-7 are required to ensure that sources can demonstrate compliance with applicable state and federal rules on a more or less continuous basis. All State and Federal rules contain compliance provisions, however, these provisions do not always fulfill the requirement for a more or less continuous demonstration. When this occurs IDEM, OAQ, in conjunction with the source, must develop specific conditions to satisfy 326 IAC 2-7-5. As a result, compliance requirements are divided into two sections: Compliance Determination Requirements and Compliance Monitoring Requirements.

Compliance Determination Requirements in Section D of the permit are those conditions that are found more or less directly within State and Federal rules and the violation of which serves as grounds for enforcement action. If these conditions are not sufficient to demonstrate continuous compliance, they will be supplemented with Compliance Monitoring Requirements, also Section D of the permit. Unlike Compliance Determination Requirements, failure to meet Compliance Monitoring conditions would serve as a trigger for corrective actions and not grounds for enforcement action. However, a violation in relation to a compliance monitoring condition will arise through a source's failure to take the appropriate corrective actions within a specific time period.

The compliance monitoring requirements applicable to this modification are as below:

1. The granulation and drying, screening, and blending processes of the Bupropion production line have applicable compliance monitoring conditions as specified below. These units are controlled by baghouses V4 and V5.
 - (a) Visible emission notations of the baghouse stack exhausts (stacks V4 and V5) shall be performed once per shift during normal daylight operations. A trained employee shall record whether emissions are normal or abnormal. For processes operated continuously, "normal" means those conditions prevailing, or expected to prevail, eighty percent (80%) of the time the process is in operation, not counting startup or shut down time. In the case of batch or discontinuous operations, readings shall be taken during that part of the operation that would normally be expected to cause the greatest emissions. A trained employee is an employee who has worked at the plant at least one (1) month and has been trained in the appearance and characteristics of normal visible emissions for that specific process. The Compliance Response Plan for this unit shall contain troubleshooting contingency and response steps for when an abnormal emission is observed. Failure to take response steps in accordance with Section C - Compliance Response Plan - Preparation, Implementation, Records and Reports shall be considered a deviation from this permit.
 - (b) Daily inspections shall be performed for the baghouses controlling the granulation and drying, screening, and blending processes. All defective bags shall be replaced. The daily inspection shall include the following:
 - (1) Walk through the system and listen for proper operation.
 - (2) Check for unusual occurrences in process.
 - (3) Check compressed-air pressure.
 - (4) Assure that dust is being removed from the system.
 - (c) In the event that bag failure has been observed:
 - (1) For multi-compartment units, the affected compartments will be shut down immediately until the failed units have been repaired or replaced.

Within eight (8) business hours of the determination of failure, response steps according to the timetable described in the Compliance Response Plan shall be initiated. For any failure with corresponding response steps and timetable not described in the Compliance Response Plan, response steps shall be devised within eight (8) business hours of discovery of the failure and shall include a timetable for completion. If operations continue after bag failure is observed and it will be ten (10) days or more after the failure is observed before the failed units will be repaired or replaced, the Permittee shall promptly notify the IDEM, OAQ of the expected date the failed units will be repaired or replaced. The notification shall also include the status of the applicable compliance monitoring parameters with respect to normal, and the results of any response actions taken up to the time of notification.

- (2) For single compartment baghouses, failed units and the associated process will be shut down immediately until the failed units have been repaired or replaced. Operations may continue only if the event qualifies as an emergency and the Permittee satisfies the requirements of the emergency provisions of this permit.

These monitoring conditions are necessary because the granulation and drying, screening, and blending process must operate properly to ensure compliance with 326 IAC 6-3-2 (Particulate Emission Limitations for Manufacturing Processes).

2. The tablet coating process of the Bupropion production line, which will be controlled by a thermal oxidizer, has applicable compliance monitoring conditions as specified below:
 - (a) Pursuant to 40 CFR 63.1258(b)(5), the Permittee shall monitor and record the outlet TOC concentration and the outlet hydrogen halide and halogen concentration every 15 minutes during the period in which the device is functioning in achieving the HAP removal required by 40 CFR 63, Subpart GGG using CEMS as specified in 40 CFR 63.1258 (b)(5)(i)(A) through (D) and 326 IAC 3-5-2. The requirements of 326 IAC 3-5 is not federally enforceable.
 - (b) A continuous temperature monitoring system shall be calibrated, maintained, and operated on the thermal oxidizer for measuring operating temperature. For purposes of this condition, continuous means no less than once per minute. The output of this system shall be recorded as a 3-hour average. From the date of issuance of this permit until the approved stack test results are available, the Permittee shall take appropriate response steps in accordance with Section C - Compliance Response Plan - Preparation, Implementation, Records, and Reports whenever the 3-hour average temperature of the thermal oxidizer is below 1,400°F. A 3-hour average temperature that is below 1,400°F is not a deviation from this permit. Failure to take response steps in accordance with Section C - Compliance Response Plan - Preparation, Implementation, Records, and Reports shall be considered a deviation from this permit.
 - (c) The Permittee shall determine the 3-hour average temperature from the most recent valid stack test that demonstrates compliance with limits in this permit, as approved by IDEM.
 - (d) On and after the date the approved stack test results are available, the Permittee shall take appropriate response steps in accordance with Section C - Compliance Response Plan - Preparation, Implementation, Records, and Reports whenever the 3-hour average temperature of the thermal oxidizer is below the 3-hour average temperature as observed during the compliant stack test. A 3-hour average temperature that is below the 3-hour average temperature as observed during the compliant stack test is not a deviation from this permit. Failure to take

response steps in accordance with Section C - Compliance Response Plan - Preparation, Implementation, Records, and Reports shall be considered a deviation from this permit.

- (e) The Permittee shall determine fan amperage or duct pressure from the most recent valid stack test that demonstrates compliance with limits in this permit, as approved by IDEM.
- (f) The duct pressure or fan amperage shall be observed at least once per day when the thermal oxidizer is in operation. When for any one reading, the duct pressure or fan amperage is outside the normal range as established in most recent compliant stack test, the Permittee shall take reasonable response steps in accordance with Section C -Compliance Response Plan - Preparation, Implementation, Records, and Reports. A reading that is outside the range as established in the most recent compliant stack test is not a deviation from this permit. Failure to take response steps in accordance with Section C - Compliance Response Plan - Preparation, Implementation, Records, and Reports shall be considered a deviation from this permit.

These monitoring conditions are necessary because the thermal oxidizer must operate properly at all times the tablet coating process is in operation to ensure compliance with 326 IAC 8-1-6 (BACT) and 40 CFR 63, Subpart GGG.

Proposed Changes

Bold language has been added, language with a line through it has been deleted. The mailing address for IDEM has been changed throughout the permit.

A.1 General Information [326 IAC 2-7-4(c)] [~~326 IAC 2-7-5(15)~~]

The Permittee owns and operates batch pharmaceutical manufacturing facility producing liquid, capsule, and tablet pharmaceuticals.

Responsible Official: ~~Leo Katalinas~~ **V.P. - Manufacturing**
Source Address: 1101 C Avenue West, Seymour, Indiana 47274
Mailing Address: 1101 C Avenue West, Seymour, Indiana 47274
SIC Code: 2834
County Location: Jackson
Source Location Status: **Nonattainment for 8-hour Ozone Standard**
Attainment for all **other** criteria pollutants
Source Status: Part 70 Permit Program
Minor Source, under PSD; **Major Source under Emission Offset;**
Major Source, Section 112 of the Clean Air Act
Not 1 of 28 Source Categories

A.2 Emission Units and Pollution Control Equipment Summary [326 IAC 2-7-4(c)(3)] [326 IAC 2-7-5(15)]

This stationary source consists of the following emission units and pollution control devices:

.....

- (b) One (1) tablet manufacturing department, constructed in 1993, consisting of
 - (1) One (1) granulation department consisting of four (4) mixers, six (6) comminuting mills and four (4) ~~electric~~ **steam-heated** production ovens, equipped with a baghouse for particulate matter control, identified as ~~V2~~ **EFDC1**.

- (2) One (1) tablet compression department consisting of one (1) granulator, and eleven (11) tablet presses, equipped with a **two (2) baghouses** for particulate matter control, identified as **V3 and V4**.
- (3) One (1) tablet coating department consisting of two (2) hi-coaters, equipped with two (2) baghouses for particulate mater control, identified as ~~V6 and V9~~ **DC04 and DC05**.
- (c) One (1) capsule manufacturing department, constructed in 1993, consisting of coating pans, auger feeders and several kettles, equipped with a baghouse for particulate matter control, identified as V5.
- (d) One (1) Phase IIIA production area, identified as emission unit ~~02 (EU-02)~~ **EFDC2**. This area manufactures several products, which involve tablet formulation, compression and filling of tablets, capsules and aqueous coating of tablets. This production area is rated at 1,960.3 pounds per batch (lbs/batch) of raw material and the PM emissions are controlled by baghouse ~~EU-02~~ **EFDC2**. The Phase IIIA production area uses 660 pounds per batch (lbs/batch) of ethanol in the coating process. The production area includes one (1) flo-coater for the application of sustained release coating, equipped with ~~two (2)~~ **one (1)** baghouses, identified as ~~V7 and V8~~. These units were constructed in 2000.
- (e) Cleaning and sanitizing operations using isopropanol, bleaches, and non-solvent based sanitizing agents.
- (f) One (1) Colyte production area (identified as emission unit ~~01 (EU-01)~~ **DC16-1**), used to manufacture different types of Colyte, involving a dry mix blending operation, product container filling and labeling. This production area was constructed in 2000 and is rated at 3,956 pounds of raw material per batch (lbs/batch) and the PM emissions are controlled by baghouse ~~EU-01~~ **DC16-1**.
- (g) **One (1) Bupropion production line, to be constructed in 2005, with a maximum throughput rate of 270 batches per year and 2,400 pounds of dry solids per batch, consisting of the following:**
 - (1) **One (1) granulation solution preparation process, consisting of the following:**
 - (A) **Two (2) mixers, each with a maximum capacity of 40 gallons.**
 - (B) **Two (2) mixers, each with a maximum capacity of 122 gallons.**
 - (C) **Alcohol storage drums.**
 - (2) **One (1) granulation and drying, screening, and blending process, using the existing baghouses V4 and V5 for particulate matter control, and exhausting to stacks EF -04 and EF-05. This process consists of the following:**
 - (A) **One (1) fluid bed dryer.**
 - (B) **One (1) Bohle bin, with a maximum capacity of 37 gallons.**
 - (C) **One (1) Bohle blender.**
 - (3) **One (1) tablet compression process.**
 - (4) **One (1) tablet coating preparation process.**

- (5) **One (1) tablet coating process, consisting of three (3) spray guns, with a maximum throughput rate of 98,947 tablets per hour, controlled by one (1) regenerative thermal oxidizer, and exhausting to stack EF 11-2.**
- (6) **One (1) tablet printing process.**
- (7) **One (1) packaging process.**

A.3 **Specifically Regulated Insignificant Activities [326 IAC 2-7-1(21)] [326 IAC 2-7-4(c)] [326 IAC 2-7-5(15)]**

...

- (d) Other categories with emissions below insignificant thresholds:

...

- (2) One (1) product weigh-up department for weighing the tablet, capsule, and liquid departments, consisting of six (6) weigh-up rooms with drums, scoops and scales, with emissions exhausted through one (1) baghouse for particulate matter control, identified as ~~V4-EFDC2~~. Particulate matter emissions before the baghouse are less than five (5) pounds per hour [326 IAC 6-3].

B.25 Credible Evidence [326 IAC 2-7-5(3)][326 IAC 2-7-6][62 FR 8314 [326 IAC 1-1-6]

For the purpose of submitting compliance certifications or establishing whether or not the Permittee has violated or is in violation of any condition of this permit, nothing in this permit shall preclude the use, including the exclusive use, of any credible evidence or information relevant to whether the Permittee would have been in compliance with the condition of this permit if the appropriate performance or compliance test or procedure had been performed.

C.11 Maintenance of Continuous Emission Monitoring Equipment [326 IAC 2-7-5(3)(A)(iii)]

- (a) **The Permittee shall install, calibrate, maintain, and operate all necessary continuous emission monitoring systems (CEMS) and related equipment.**
- (b) **In the event that a breakdown of a continuous emission monitoring system occurs, a record shall be made of the times and reasons of the breakdown and efforts made to correct the problem.**
- (c) **Nothing in this permit shall excuse the Permittee from complying with the requirements to operate a continuous emission monitoring system pursuant to 40 CFR 63, Subpart GGG.**

C.4412 Monitoring Methods [326 IAC 3] [40 CFR 60] [40 CFR 63]

C.4213 Pressure Gauge and Other Instrument Specifications [326 IAC 2-1.1-11] [326 IAC 2-7-5(3)] [326 IAC 2-7-6(1)]

- (a) **Whenever a condition in this permit requires the measurement of pressure drop across any part of the unit or its control device, the gauge employed shall have a scale such that the expected normal reading shall be no less than twenty percent (20%) of full scale and be accurate within plus or minus two percent (±2%) of full scale reading.**
- (b) **Whenever a condition in this permit requires the measurement of a temperature, the instrument employed shall have a scale such that the expected normal reading shall be no less than twenty percent (20%) of full scale and be accurate within plus or minus two percent (±2%) of full scale reading.**

- (bc) The Permittee may request the IDEM, OAQ approve the use of a pressure gauge or other instrument that does not meet the above specifications provided the Permittee can demonstrate an alternative pressure gauge or other instrument specification will adequately ensure compliance with permit conditions requiring the measurement of pressure drop or other parameters.

C.4314 Emergency Reduction Plans [326 IAC 1-5-2] [326 IAC 1-5-3]

C.4415 Risk Management Plan [326 IAC 2-7-5(12)] [40 CFR 68.215]

C.4516 Compliance Response Plan - Preparation, Implementation, Records, and Reports [326 IAC 2-7-5]
[326 IAC 2-7-6]

C.4617 Actions Related to Noncompliance Demonstrated by a Stack Test [326 IAC 2-7-5]
[326 IAC 2-7-6]

C.4718 Emission Statement [326 IAC 2-7-5(3)(C)(iii)] [326 IAC 2-7-5(7)] [326 IAC 2-7-19(c)]
[326 IAC 2-6]

C.4819 General Record Keeping Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-6]

C.4920 General Reporting Requirements [326 IAC 2-7-5(3)(C)] [326 IAC 2-1.1-11]

C.2921 Compliance with 40 CFR 82 and 326 IAC 22-1

SECTION D.2

FACILITY OPERATION CONDITIONS

Facility Description [326 IAC 2-7-5(15)]:

- (b) One (1) tablet manufacturing department, constructed in 1993, consisting of
 - (1) One (1) granulation department consisting of four (4) mixers, six (6) comminuting mills and four (4) ~~electric~~ **steam-heated** production ovens, equipped with a baghouse for particulate matter control, identified as ~~V2~~ **EFDC1**.
 - (2) One (1) tablet compression department consisting of one (1) granulator, and eleven (11) tablet presses, equipped with a **two (2)** baghouses for particulate matter control, identified as **V3 and V4**.
 - (3) One (1) tablet coating department consisting of two (2) hi-coaters, equipped with two (2) baghouses for particulate matter control, identified as ~~V6 and V9~~ **DC04 and DC05**.
- (c) One (1) capsule manufacturing department, constructed in 1993, consisting of coating pans, auger feeders and several kettles, equipped with a baghouse for particulate matter control, identified as V5.
- (d) One (1) Phase IIIA production area, identified as emission unit ~~02 (EU-02)~~ **EFDC2**. This area manufactures several products, which involve tablet formulation, compression and filling of tablets, capsules and aqueous coating of tablets. This production area is rated at 1,960.3 pounds per batch (lbs/batch) of raw material and the PM emissions are controlled by baghouse **EU-02-~~EFDC2~~**. The Phase IIIA production area uses 660 pounds per batch (lbs/batch) of ethanol in the coating process. The production area includes one (1) flo-coater for the application of sustained release coating, equipped with ~~two (2)~~ **one (1)** baghouses, identified as ~~V7 and V8~~. These units were constructed in 2000.
- (e) Cleaning and sanitizing operations using isopropanol, bleaches, and non-solvent based sanitizing agents.

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

~~D.2.9 Parametric Monitoring~~

~~The Permittee shall record the total static pressure drop across the baghouses V2, V4, V5, V6, V7, V8, V9 and EU-02 used in conjunction with the tablet, capsule, and phase IIIA manufacturing facilities, at least once per shift when these facilities are in operation when venting to the atmosphere. When for any one reading, the pressure drop across the baghouses (V2, V4, V5, V6, V7, V8, V9, and EU-02) is outside the range of 0.1 and 6.0 inches of water or a range established during the latest stack test the Permittee shall take reasonable response steps in accordance with Section C - Compliance Response Plan. A pressure reading that is outside the above mentioned range is not a deviation from this permit. Failure to take response steps in accordance with Section C - Compliance Response Plan - Preparation, Implementation, Records, and Reports, shall be considered a deviation from this permit.~~

~~The instrument used for determining the pressure shall comply with Section C - Pressure Gauge and Other Instruments Specifications, of this permit, shall be subject to approval by IDEM, OAQ, and shall be calibrated at least once every six (6) months.~~

~~D.2.9 Baghouse Inspections~~

~~Daily inspections shall be performed for the baghouses controlling the tablet, capsule, and phase IIIA manufacturing facilities. All defective bags shall be replaced. The daily inspection shall include the following:~~

- (a) **Walk through the system and listen for proper operation.**
- (b) **Check for unusual occurrences in process.**
- (c) **Check compressed-air pressure.**
- (d) **Assure that dust is being removed from the system.**

~~D.2.10 Baghouse Inspections~~

~~An inspection shall be performed each calendar quarter of all bags controlling the tablet, capsule, and phase IIIA manufacturing facilities when venting to the atmosphere. A baghouse inspection shall be performed within three months of redirecting vents to the atmosphere and every three months thereafter. Inspections are optional when venting to the indoors. All defective bags shall be replaced.~~

~~D.2.110 Broken or Failed Bag Detection~~

~~D.2.1211 Record Keeping Requirements~~

- (a) To document compliance with Condition D.2.8, the Permittee shall maintain records of visible emission notations of the tablet, capsule and phase IIIA manufacturing facilities stack exhaust once per shift.
- ~~(b) To document compliance with Condition D.2.9, the Permittee shall maintain the following:~~
 - ~~(1) Once per shift records of the following operational parameters during normal operation when venting to the atmosphere:~~
 - ~~(A) Inlet and outlet differential static pressure; and~~
 - ~~(B) Cleaning cycle operation.~~
 - ~~(2) Documentation of the dates vents are redirected.~~
- (eb) To document compliance with Condition D.2.409, the Permittee shall maintain records of the results of the inspections required under Condition D.2.409 and the dates the vents are redirected.
- (ec) To document compliance with Condition D.2.2, the Permittee shall maintain monthly logs of information pertaining to the usage and handling of volatile organic solvents and the implementation of the flo-coaters.
- (ed) To document compliance with Condition D.2.3 and D.2.7, the Permittee shall keep records showing the HAP concentrations of all vent streams and the information necessary to support how the HAP concentrations were determined.
- (fe) All records shall be maintained in accordance with Section C - General Record Keeping Requirements, of this permit.

~~D.2.1312 Record Keeping Requirements for 40 CFR 63, Subpart GGG~~

~~D.2.1413 Reporting Requirements for 40 CFR 63, Subpart GGG~~

SECTION D.3

FACILITY OPERATION CONDITIONS

Facility Description [326 IAC 2-7-5(15)]:

- (f) One (1) Colyte production area (identified as emission unit ~~01 (EU-01)~~ **DC16-1**), used to manufacture different types of Colyte, involving a dry mix blending operation, product container filling and labeling. This production area was constructed in 2000 and is rated at 3,956 pounds of raw material per batch (lbs/batch) and the PM emissions are controlled by baghouse ~~EU-04~~ **DC16-1**.

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

SECTION D.4

FACILITY OPERATION CONDITIONS

Facility Description [326 IAC 2-7-5(15)]: Insignificant Activities

- (a) Natural gas-fired combustion sources with heat input equal to or less than ten million (10,000,000) Btu per hour, constructed between 1985 and 2000, including:
- (1) One (1) natural gas-fired boiler with maximum capacity of 4.8 MMBtu per hour [326 IAC 6-2-4];
 - (2) One (1) natural gas-fired boiler with maximum capacity of 3.6 MMBtu per hour [326 IAC 6-2-4]; and
- (b) The following equipment related to manufacturing activities not resulting in the emission of HAPs: brazing equipment, cutting torches, soldering equipment, welding equipment [326 IAC 6-3].
- (c) Paved and unpaved roads and parking lots with public access [326 IAC 6-4].
- (d) Other categories with emissions below insignificant thresholds:
- (1) A liquid pharmaceutical manufacturing facility, consisting of liquid blending, filtration, and packaging, emitting less than three (3) pounds per hour of VOC.
 - (2) One (1) product weigh-up department for weighing the tablet, capsule, and liquid departments, consisting of six (6) weigh-up rooms with drums, scoops and scales, with emissions exhausted through one (1) baghouse for particulate matter control, identified as ~~V4~~ **EFDC2**. Particulate matter emissions before the baghouse are less than five (5) pounds per hour [326 IAC 6-3].

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

SECTION D.5

FACILITY OPERATION CONDITIONS

Facility Description [326 IAC 2-7-5(15)]:

- (g) One (1) Bupropion production line, to be constructed in 2005, with a maximum throughput rate of 270 batches per year and 2,400 pounds of dry solids per batch, consisting of the following:
- (1) One (1) granulation solution preparation process, consisting of the following:
 - (A) Two (2) mixers, each with a maximum capacity of 40 gallons.
 - (B) Two (2) mixers, each with a maximum capacity of 122 gallons.
 - (C) Alcohol storage drums.
 - (2) One (1) granulation and drying, screening, and blending process, using the existing baghouses V4 and V5 for particulate matter control, and exhausting to stacks EF -04 and EF-05. This process consists of the following:
 - (A) One (1) fluid bed dryer.
 - (B) One (1) Bohle bin, with a maximum capacity of 37 gallons.
 - (C) One (1) Bohle blender.
 - (3) One (1) tablet compression process.
 - (4) One (1) tablet coating preparation process.
 - (5) One (1) tablet coating process, consisting of three (3) spray guns, with a maximum throughput rate of 98,947 tablets per hour, controlled by one (1) regenerative thermal oxidizer, and exhausting to stack EF 11-2.
 - (6) One (1) tablet printing process.
 - (7) One (1) packaging process

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

Emission Limitations and Standards [326 IAC 2-7-5(1)]

D.5.1 VOC Emissions [326 IAC 8-1-6]

Pursuant to 326 IAC 8-1-6 (BACT), the Permittee shall control the VOC emissions from the tablet coating process with a Best Available Control Technology (BACT), which has been determined to be the following:

- (a) The VOC emissions from the tablet coating process of the Bupropion production line shall be controlled by a thermal oxidizer.
- (b) The destruction efficiency for thermal oxidizer shall be at least 98%.
- (c) The capture efficiency shall be 100% as defined in EPA Method 204.
- (d) The VOC emissions from thermal oxidizer shall not exceed 0.70 lbs/hr.

D.5.2 General Provisions Relating to NESHAPs [326 IAC 20-1] [40 CFR 63, Subpart A]

The provisions of 40 CFR 63, Subpart A - General Provisions, which are incorporated by reference in 326 IAC 20-1, apply to the facilities and operations described in this section except when otherwise specified in 40 CFR 63, Subpart GGG.

D.5.3 National Emission Standards for Pharmaceuticals Production [326 IAC 20-1][40 CFR 63, Subpart GGG]

The Bupropion production line is subject to the requirements of 40 CFR 63, Subpart GGG and the Permittee shall comply with the following applicable requirements:

- (a) Pursuant to 40 CFR 63.1254(c), the process vents of the tablet coating process shall route to a combustion control device achieving an outlet TOC concentration, as calibrated on methane or the predominant HAP, of 20 ppmv or less, and an outlet concentration of hydrogen halides and halogens of 20 ppmv or less.
- (b) The control device (thermal oxidizer) of the tablet coating process shall comply with the equipment leak standards specified in 40 CFR 63.1255.

D.5.4 Particulate Matter (PM) [326 IAC 6-3-2]

Particulate emissions from each of the granulation and drying, screening, and blending processes shall not exceed 0.64 lbs/hr when the process weight rate is 126 lbs/hr.

The pounds per hour limitation was calculated with the following equation:

Interpolation of the data for the process weight rate up to sixty thousand (60,000) pounds per hour shall be accomplished by use of the equation:

$$E = 4.10 P^{0.67} \quad \text{where } E = \text{rate of emission in pounds per hour and} \\ P = \text{process weight rate in tons per hour}$$

D.5.5 Preventive Maintenance Plan [326 IAC 2-7-5(13)]

A Preventive Maintenance Plan, in accordance with Section B - Preventive Maintenance Plan, of this permit, is required for these facilities and their control devices.

Compliance Determination Requirements

D.5.6 VOC Control

In order to comply with Conditions D.5.1 and D.5.3, the regenerative thermal oxidizer shall be in operation and control emissions from the tablet coating process at all times that this process is in operation.

D.5.7 Particulate Matter (PM)

In order to comply with Condition D.5.4, the baghouses V4 and V5 for PM control shall be in operation and control emissions from the granulation and drying, screening, and blending processes at all times that these facilities are in operation.

D.5.8 Testing Requirements [326 IAC 2-7-6(1),(6)] [326 IAC 2-1.1-11] [326 IAC 8-1-6]

In order to demonstrate compliance with Condition D.5.1, the Permittee shall perform VOC (including emission rate and capture and destruction efficiency) testing for the thermal oxidizer equipped with the tablet coating process, within 60 days after achieving the maximum production, but not later than 180 days after initial startup, utilizing methods as approved by the Commissioner. This test shall be repeated at least once every five (5) years from the date of this valid compliance demonstration. Testing shall be conducted in accordance with Section C - Performance Testing.

D.5.9 National Emission Standards for Pharmaceuticals Production [326 IAC 20-1][40 CFR 63, Subpart GGG]

Pursuant to 40 CFR 63.1257(a)(5), in order to demonstrate initial compliance with the alternative standard in 40 CFR 63.1254(c) and Condition D.5.3(a), the Permittee shall be in compliance with the monitoring provisions in 40 CFR 63.1258(b)(5) upon the start-up of Bupropion production line. The Permittee shall use Method 18 to determine the predominant organic HAP in the emission stream if the TOC monitor is calibrated on the predominant HAP.

Compliance Monitoring Requirements [326 IAC 2-7-6(1)] [326 IAC 2-7-5(1)]

D.5.10 Continuous Emissions Monitoring [326 IAC 20-1] [40 CFR 63, Subpart GGG] [326 IAC 3-5-2]

Pursuant to 40 CFR 63.1258(b)(5), the Permittee shall monitor and record the outlet TOC concentration and the outlet hydrogen halide and halogen concentration every 15 minutes during the period in which the device is functioning in achieving the HAP removal required by 40 CFR 63, Subpart GGG using CEMS as specified in 40 CFR 63.1258 (b)(5)(i)(A) through (D) and 326 IAC 3-5-2. The requirements of 326 IAC 3-5 is not federally enforceable.

D.5.11 Visible Emissions Notations

- (a) Visible emission notations of the granulation and drying, screening, and blending processes exhausts shall be performed once per shift during normal daylight operations when exhausting to the atmosphere. A trained employee shall record whether emissions are normal or abnormal.
- (b) For processes operated continuously, "normal" means those conditions prevailing, or expected to prevail, eighty percent (80%) of the time the process is in operation, not counting startup or shut down time.
- (c) In the case of batch or discontinuous operations, readings shall be taken during that part of the operation that would normally be expected to cause the greatest emissions.
- (d) A trained employee is an employee who has worked at the plant at least one (1) month and has been trained in the appearance and characteristics of normal visible emissions for that specific process.
- (e) The Compliance Response Plan for this unit shall contain troubleshooting contingency and response steps for when an abnormal emission is observed. Failure to take response steps in accordance with Section C - Compliance Response Plan - Preparation, Implementation, Records and Reports shall be considered a deviation from this permit.

D.5.12 Thermal Oxidizer Temperature

- (a) A continuous monitoring system shall be calibrated, maintained, and operated on the thermal oxidizer for measuring operating temperature. For the purpose of this condition, continuous means no less than once per minute. The output of this system shall be recorded as a 3-hour average. From the date of issuance of this permit until the approved stack test results are available, the Permittee shall operate the thermal oxidizer at or above the hourly average temperature of 1,400°F.
- (b) The Permittee shall determine the 3-hour average temperature from the most recent valid stack test that demonstrates compliance with limits in Conditions D.5.1 and D.5.3, as approved by IDEM.
- (c) On and after the date the approved stack test results are available, the Permittee shall operate the thermal oxidizer at or above the 3-hour average temperature as observed during the compliant stack test.

D.5.13 Parametric Monitoring

- (a) The Permittee shall determine the appropriate duct pressure or fan amperage from the most recent valid stack test that demonstrates compliance with limits in Conditions D.5.1 and D.5.3, as approved by IDEM.
- (b) The duct pressure or fan amperage shall be observed at least once per day when the thermal oxidizer is in operation. On and after the date the approved stack test results are available, the duct pressure or fan amperage shall be maintained within the normal range as established in most recent compliant stack test.

D.5.14 Baghouse Inspections

Daily inspections shall be performed for the baghouses controlling the granulation and drying, screening, and blending processes. All defective bags shall be replaced. The daily inspection shall include the following:

- (a) Walk through the system and listen for proper operation.
- (b) Check for unusual occurrences in process.
- (c) Check compressed-air pressure.
- (d) Assure that dust is being removed from the system.

D.5.15 Broken or Failed Bag Detection

In the event that bag failure has been observed:

- (a) For multi-compartment units, the affected compartments will be shut down immediately until the failed units have been repaired or replaced. Within eight (8) business hours of the determination of failure, response steps according to the timetable described in the Compliance Response Plan shall be initiated. For any failure with corresponding response steps and timetable not described in the Compliance Response Plan, response steps shall be devised within eight (8) business hours of discovery of the failure and shall include a timetable for completion. Failure to take response steps in accordance with Section C - Compliance Response Plan -Preparation, Implementation, Records, and Reports, shall be considered a deviation from this permit. If operations continue after bag failure is observed and it will be 10 days or more after the failure is observed before the failed units will be repaired or replaced, the Permittee shall promptly notify the IDEM, OAQ of the expected date the failed units will be repaired or replaced. The notification shall also include the status of the applicable compliance monitoring parameters with respect to normal, and the results of any response actions taken up to the time of notification.
- (b) For single compartment baghouses, if failure is indicated by a significant drop in the baghouse's pressure readings with abnormal visible emissions or the failure is indicated by an opacity violation, or if bag failure is determined by other means, such as gas temperatures, flow rates, air infiltration, leaks, dust traces or triboflows, then failed units and the associated process will be shut down immediately until the failed units have been repaired or replaced. Operations may continue only if the event qualifies as an emergency and the Permittee satisfies the requirements of the emergency provisions of this permit (Section B - Emergency Provisions).

Record Keeping and Reporting Requirement [326 IAC 2-7-5(3)] [326 IAC 2-7-19]

D.5.16 Record Keeping Requirements

- (a) To document compliance with Condition D.5.10, the Permittee shall maintain records of the CEM data for the outlet TOC concentration, and the outlet hydrogen halide and halogen concentration.
- (b) To document compliance with Condition D.5.11, the Permittee shall maintain records of visible emission notations of the granulation and drying, screening, and blending processes stack exhausts once per shift.
- (c) To document compliance with Condition D.5.12, the Permittee shall maintain continuous temperature records for the thermal oxidizer and the 3-hour average temperature used to demonstrate compliance during the most recent compliant stack test.
- (d) To document compliance with Condition D.5.13, the Permittee shall maintain daily records of the duct pressure or fan amperage for the thermal oxidizer/heat recovery steam generator.
- (e) To document compliance with Conditions D.5.14, the Permittee shall maintain records of the results of the inspections required under Condition D.5.14.
- (f) To document compliance with Condition D.5.5, the Permittee shall maintain records of any additional inspections prescribed by the Preventive Maintenance Plan.
- (g) All records shall be maintained in accordance with Section C - General Record Keeping Requirements, of this permit.

D.5.17 Record Keeping Requirements for 40 CFR 63, Subpart GGG [40 CFR 63.1259]

Pursuant to 40 CFR 63.1259, the Permittee shall keep the following records:

- (a) The record keeping requirements in 40 CFR 63, Subpart A.
- (b) Records of equipment operations.
- (c) Operating scenarios.
- (d) Equipment leak detection and repair programs.
- (e) Records of inspections.

D.5.18 Reporting Requirements for 40 CFR 63, Subpart GGG [40 CFR 63.1260]

Pursuant to 40 CFR 63.1260, the Permittee shall comply with the following reporting requirements:

- (a) Initial notification in accordance with 40 CFR 63.9(b) or (d)
- (b) Notification of CMS performance evaluation as specified in 40 CFR 63.1259(d).
- (c) Notification of compliance status report as specified in 40 CFR 63.1259(f).
- (e) Periodic reports as specified in 40 CFR 63.1259(g).
- (f) Notification of process change.
- (i) Reports of startup, shut down, and malfunction.

Conclusion

The construction of this proposed modification shall be subject to the conditions of the attached proposed Part 70 Significant Source Modification No. 071-18489-00023. The operation of this proposed modification shall be subject to the conditions of the attached proposed Part 70 Significant Permit Modification No. 071-18639-00023.

**Appendix A: Emission Calculations
VOC and PM/PM10 Emissions
From the Tablet Coating Process**

**Company Name: Schwarz Pharma Manufacturing, Inc.
Address : 1101 C Avenue West, Seymour, IN 47274
SPM: 071-18639-00023
Reviewer: ERG/YC
Date: May 23, 2005**

Material	Density (lbs/gal)	Weight % VOC	Maximum Throughput (batches/yr)	Maximum Usage (lbs/batch)*	PTE of VOC before Control (tons/yr)	RTO Control Efficiency (%)**	PTE of VOC after Control (tons/yr)	Transfer Efficiency (%)	PTE of PM/PM10 before Control (tons/yr)
SDA-3A	6.60	100%	270	1,111	150	98.0%	3.00	100%	0.00
Colorcon Black	11.7	85.0%	270	11.02	1.26	98.0%	0.03	40.0%	0.13
Total					151		3.02		0.13

* This is the worst case scenario between making 100 mg tablets and 150 mg tablets.

** This coating process is controlled by a RTO with a control efficiency of 98%.

METHODOLOGY

PTE of VOC before Control (tons/yr) = Max. Throughput (batch/yr) x Max. Usage (lbs/batch) x Weight % VOC (%) x 1 ton/2000 lbs

PTE of VOC after Control (tons/yr) = PTE of VOC before Control (tons/yr) x (1-RTO Control Efficiency)

PTE of PM/PM10 before Control (tons/yr) = Max. Throughput (batch/yr) x Max. Usage (lbs/batch) x (1- Weight % VOC) x (1-Transfer efficiency) x (1 ton/2000 lbs)

Appendix A: Emission Calculations
HAP Emissions
From the Tablet Coating Process

Company Name: Schwarz Pharma Manufacturing, Inc.
Address : 1101 C Avenue West, Seymour, IN 47274
SPM: 071-18639-00023
Reviewer: ERG/YC
Date: May 23, 2005

Material	Density (lbs/gal)	Maximum Throughput (batches/yr)	Maximum Usage (lbs/batch)*	Weight % Methanol	PTE of Methanol before Control (tons/yr)	RTO Control Efficiency**	PTE of Methanol after Control (tons/yr)
SDA-3A	6.60	270	1,111	4.70%	7.05	98.0%	0.14
Colorcon Black	11.7	270	11.02	8.00%	0.12	98.0%	2.38E-03
Total					7.17		0.14

* This is the worst case scenario between making 100 mg tablets and 150 mg tablets.

** This coating process is controlled by a RTO with a control efficiency of 98%.

METHODOLOGY

PTE of HAP before Control (tons/yr) = Max. Throughput (batch/yr) x Max. Usage (lbs/batch) x Weight % HAP x 1 ton/2000 lbs

PTE of HAP after Control (tons/yr) = PTE of HAP before Control (tons/yr) x (1 - RTO Control Efficiency)

Appendix A: Emission Calculations
PM/PM10 Emissions
From the Tablet Granulation and Drying, Screening, and Blending process

Company Name: Schwarz Pharma Manufacturing, Inc.
Address : 1101 C Avenue West, Seymour, IN 47274
SPM: 071-18639-00023
Reviewer: ERG/YC
Date: May 23, 2005

Process Description:

PM Control Equipment: Existing Baghouses V4 and V5
Grain Loading: 0.01 grains/dscf
Air Flow Rate: 580 dscf/min/baghouse
Control Efficiency: 99.9%

1. Potential to Emit After Control:

Assume all the PM emissions are equal to PM10 emissions.

Hourly PM/PM10 Emissions = $0.01 \text{ (gr/dscf)} \times 580 \text{ (dscf/min)} \times 60 \text{ (min/hr)} \times 1/7000 \text{ (lbs/gr)} =$ **0.05 lbs/hr/baghouse**
Annual PM/PM10 emissions = $0.05 \text{ lbs/hr/baghouse} \times 8760 \text{ hr/yr} \times 1 \text{ ton}/2000 \text{ lbs} \times 2 \text{ baghouses} =$ **0.44 tons/yr**

2. Potential to Emit Before Control:

PTE of PM/PM10 Before Control = $0.44 \text{ tons/yr} / (1-99.9\% \text{ Control Efficiency}) =$ **435 tons/yr**

**Appendix A: Emission Calculations
Natural Gas Combustion
(MMBtu/hr < 100)
From 0.22 MMBtu/hr Thermal Oxidizer**

**Company Name: Schwarz Pharma Manufacturing, Inc.
Address : 1101 C Avenue West, Seymour, IN 47274
SPM: 071-18639-00023
Reviewer: ERG/YC
Date: May 23, 2005**

Heat Input Capacity
MMBtu/hr

Potential Throughput
MMCF/yr

0.2

1.9

	Pollutant					
	PM*	PM10*	SO ₂	**NO _x	VOC	CO
Emission Factor in lbs/MMCF	7.6	7.6	0.6	100	5.5	84.0
Potential to Emit in tons/yr	0.01	0.01	5.8E-04	0.10	0.01	0.08

*PM and PM10 emission factors are condensable and filterable PM10 combined.

**Emission factors for NO_x: Uncontrolled = 100 lbs/MMCF.

Emission factors are from AP-42, Chapter 1.4, Tables 1.4-1, 1.4-2, and 1.4-3, SCC #1-02-006-02, 1-01-006-02, 1-03-006-02, and 1-03-006-03 (AP-42 Supplement D 3/98)

Methodology

All emission factors are based on normal firing.

MMBtu = 1,000,000 Btu

MMCF = 1,000,000 Cubic Feet of Gas

Potential Throughput (MMCF/yr) = Heat Input Capacity (MMBtu/hr) x 8,760 hrs/yr x 1 MMCF/1,000 MMBtu

Potential to Emit (tons/yr) = Potential Throughput (MMCF/yr) x Emission Factor (lbs/MMCF) x 1 ton/2000 lbs